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IN THE

Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL,
Petitioner,

v.

LEROY CARHART, *et al.*,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR STEPHEN CHASEN, M.D., MARK I. EVANS, M.D., CASSING HAMMOND, M.D., MARC HELLER, M.D., TIMOTHY R.B. JOHNSON, M.D., GERSON WEISS, M.D., CAROLYN WESTHOFF, M.D., M.SC., AND NATIONAL ABORTION FEDERATION AS *AMICUS CURIAE* SUPPORTING RESPONDENTS

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INTEREST OF AMICI[1]

Amici are plaintiffs in *National Abortion Federation* v. *Gonzales*,[2] an action brought in the United States District Court for the Southern District of New York challenging the same statute under review here, the Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531 (the "Act"). *Amici* submit this brief in support of Respondents and in support of affirmance.

Amici include seven individual physicians who are all practicing obstetrician-gynecologists, fellows of the American College of Obstetricians and Gynecologists ("ACOG"), and professors in, or chairs of, the Obstetrics and Gynecology Departments of leading teaching hospitals throughout the country. Collectively, they have published over 600 peer-reviewed articles, served as editors of numerous medical journals, and received tens of millions of dollars in competitive research grants from the National Institutes of Health. These physician-plaintiffs perform and teach abortion procedures that are banned by the Act:

- **Stephen Chasen, M.D.**, is Associate Professor of Obstetrics and Gynecology at the Weill Medical College of Cornell University and Director of High-Risk Obstetrics at New York Presbyterian-New York Weill Cornell Medical Center.

- **Mark I. Evans, M.D.**, is Professor of Obstetrics and Gynecology and Director of Comprehensive Genetics at Mount Sinai School of Medicine in New York; he is

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[1] No counsel for a party authored this brief in whole or in part, and no person or entity other than *amici* and their counsel made any monetary contribution toward the preparation or submission of this brief. Letters indicating the parties' consent to the filing of this *amicus* brief have been submitted to the Clerk of this Court.

[2] *National Abortion Fed'n* v. *Ashcroft*, 330 F. Supp. 2d 436 (S.D.N.Y. 2004), *aff'd National Abortion Fed'n* v. *Gonzales*, 437 F. 3d 278 (2d Cir. 2006).

also President of the Fetal Medicine Foundation of America.

- **Cassing Hammond, M.D.**, is Assistant Professor in Obstetrics and Gynecology and Director of the Program and Fellowship in Family Planning and Contraception at the Northwestern University School of Medicine.

- **Marc Heller, M.D.**, is the Medical Director of Planned Parenthood Mohawk Hudson in Schenectady, New York, and a part-time Associate Clinical Professor at the College of Physicians and Surgeons of Columbia University, through his association with its affiliate, Bassett Healthcare.

- **Timothy R. B. Johnson, M.D.**, a maternal-fetal medicine specialist, is the Bates Professor of the Diseases of Women and Children and Professor and Chair of the Department of Obstetrics and Gynecology at the University of Michigan Medical School.

- **Gerson Weiss, M.D.**, is Professor and Chair of the Department of Obstetrics, Gynecology, and Women's Health at the UMDNJ-New Jersey Medical School and Chief of Service of Obstetrics and Gynecology at the UMDNJ-University Hospital.

- **Carolyn Westhoff, M.D., M. Sc.**, is Professor of Obstetrics and Gynecology in the College of Physicians & Surgeons of Columbia University, as well as Professor of Epidemiology and of Population & Family Health in the Mailman School of Public Health, also at Columbia University.

Amicus **National Abortion Federation** ("NAF"), a non-profit organization founded in 1977, is the medical professional association of abortion providers in North America. Its members include over 400 non-profit and private clinics,

women's health centers, hospitals, and private physicians' offices in 47 states. NAF's members care for over half the women who obtain abortions each year in the United States, and they perform and teach abortion procedures that are banned by the Act. NAF is the lead plaintiff in *NAF* v. *Gonzales*.

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici, plaintiffs in *NAF* v. *Gonzales* ("Plaintiffs"), challenged the Act because it is constitutionally deficient on numerous grounds, including that it bans an array of safe abortion procedures. But even if the Act prohibited only second-trimester surgical abortions in which the fetus is removed intact—as the government sometimes claims—it would still unconstitutionally endanger women's health. *Amici* refer to these procedures as intact dilation and evacuation ("intact D&E"), because they are among the variants of dilation and evacuation ("D&E"), which collectively account for the vast majority of second-trimester abortions.

Essentially ignoring the Act's other flaws, the government's defense of the Act relies almost entirely on Congress's finding that intact D&Es are "never medically indicated to preserve the health of the mother." *See* Pet. Br. 2. This claim—and Congress's findings—were discredited by overwhelming evidence presented at three separate federal-court trials held simultaneously in the Spring of 2004. At those trials, eminent experts from the faculties of leading medical schools, who have years of experience both performing abortions and treating women facing high-risk pregnancies, testified that D&E with intact removal offers significant safety advantages over alternative methods of terminating a pregnancy in the second trimester. These witnesses testified to the considerable health benefits of removing the fetus as intact as possible, and to the particular benefits of doing so for women in compromised medical states. After hearing this evidence, all three district courts concluded that banning such procedures without a health exception violates the Constitution and this Court's clear commands.

The New York district court, like the Nebraska and California courts whose decisions are under review, concluded that Congress's legislative findings cannot withstand even the most deferential review. *NAF*, 330 F. Supp. 2d at 488. The New York court found that there is "no consensus that D&X is never medically necessary," *id.* at 482, and that, in fact, "there is a significant body of medical opinion that holds the contrary," *id.* The New York court's conclusions were based on a substantial record amassed from over twenty witnesses, from twelve of the most acclaimed medical and academic institutions in the country, during a three-week trial. The record in New York comports fully with those under review in this case[3] and in *Planned Parenthood Federation of America* v. *Ashcroft*, 320 F. Supp. 2d 957 (N.D. Cal. 2004) ("*PPFA*").[4] That the New York court did not credit certain of Plaintiffs' evidence does not undermine that court's central and dispositive finding: that there is substantial medical authority supporting the proposition that prohibiting intact D&E endangers women's health. This finding adds considerable further weight to support affirmance.

STATEMENT OF RELEVANT FACTS FROM NEW YORK RECORD

Procedural History of the New York Litigation

In November 2003, roughly simultaneously with the filing of the two cases currently under review by this Court, Plaintiffs brought suit in the United States District Court for the Southern District of New York challenging the Act. On November 6, 2003, the New York court issued a temporary restraining order and, with the consent of the government, later extended the TRO pending final resolution of the

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[3] *Carhart* v. *Ashcroft*, 331 F. Supp. 2d 805 (D. Neb. 2004), *aff'd Carhart* v. *Gonzales*, 413 F.3d 791 (8th Cir. 2005), *cert granted* 126 S. Ct. 1314 (2006).

[4] *Aff'd Planned Parenthood Federation of America, Inc.* v. *Gonzales*, 435 F.3d 1163 (9th Cir. 2006), *cert. granted* 126 S. Ct. 2901 (2006).

case. During a three-week trial in March and April 2004, the court heard testimony from sixteen witnesses in person and six by deposition. On August 26, 2004, the court issued a decision permanently enjoining the Act as unconstitutional under this Court's precedents because it lacks a health exception. On January 31, 2006, the Second Circuit affirmed, holding that "the lack of a health exception renders the Act unconstitutional." *NAF*, 437 F.3d at 281. The Second Circuit deferred ruling on the appropriate remedy until supplemental briefs could be filed addressing this Court's recent ruling in *Ayotte* v. *Planned Parenthood*, 126 S. Ct. 961 (2006). That briefing was thereafter stayed pending the outcome of this case.

Expert Witnesses in the New York Case

The New York court recognized seven of Plaintiffs' witnesses (including the five Plaintiffs who testified at trial) as experts in obstetrics and gynecology and abortion practice and procedures. These experts are all professors in the obstetrics and gynecology departments at leading medical schools. *See NAF*, 330 F. Supp. 2d at 458-62. Dr. Timothy Johnson is department chair at the University of Michigan; Dr. Gerson Weiss is department chair at UMDNJ-New Jersey Medical School; Drs. Amos Grunebaum and Stephen Chasen teach at Cornell University; Drs. Cassing Hammond and Marilynn Frederiksen teach at Northwestern University; and Dr. Carolyn Westhoff teaches at Columbia University. Collectively, they have extensive experience both performing and teaching the abortion methods at issue in this case. They have all performed first- and second-trimester abortions, and have used both of the procedures commonly used to terminate pregnancies in the second trimester, D&E and induction. Each of these experts has either performed, or personally observed, the variant of D&E involving intact removal of the fetus. *See* Tr. 210:8-213:12, 307:17-308:4, 312:1-7 (Grunebaum); Tr. 526:1-530:8, 533:9-20 (Hammond); Tr. 742:5-751:4 (Westhoff); Tr. 1043:5-1046:2 (Frederiksen); Tr. 1311:1-1316:25, 1338:12-1340:11, 1341:7-21 (Weiss); Tr. 1551:12-1555:13 (Chasen); *see also* Tr. 396:4-400:11 (John-

son).[5] These experts teach an array of obstetric and gynecological procedures, including abortion; most of them teach D&E with intact removal.[6]

Five experts testified at trial for the government. Each of the government's experts had limited, if any, experience with abortion practice. Tr. 1788:25-1789:21 (government's witness Lockwood); Tr. 2399:19-24 (government's witness Clark) (testifying that he considers himself only "moderately skilled" in performing abortions); Tr. 2093:2-6 (government's witness Sprang) (testifying that he has performed abortions "exceedingly rarely"); Tr. 1967:16-17 (government's witness Anand) (testifying that he has never performed any type of abortion); Tr. 2487:21-2488:15 (government's witness Cook) (testifying that he has performed abortions by methods other than induction only on "rare occasions" and that most of the abortions he performed were to remove dead fetuses). Not one of the government's experts had any experience with D&E involving intact removal. None had even personally observed such a procedure. *NAF*, 330 F. Supp. 2d at 462-64.

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[5] The portions of the trial transcript cited in this brief are reproduced in the accompanying Appendix.

[6] The New York record also included deposition testimony of Drs. Mitchell Creinin and Maureen Paul, both of whom have extensive experience in obstetrics, gynecology, and abortion practice; Dr. Watson Bowes, whom the government had designated as an expert but did not call at trial; and representatives from three medical organizations opposing the Act: Joanna Cain, M.D., chair of the ethics committee of the American College of Obstetricians and Gynecologists ("ACOG"); Meghan Kissell, Director for Communications and Advocacy for the American Medical Women's Association ("AMWA"); and Alan Baker, Chief of Staff for the American Public Health Association ("APHA"). In addition, Dr. Rebecca Baergen of Cornell-Weill Medical School testified for Plaintiffs as an expert in pathology and perinatal pathology, Tr. 1096:23-1097:3; Dr. Sherwin Nuland of Yale University, a Pulitzer Prize-winning author and expert on medical and surgical history, testified as an expert in the evolution of surgical procedures, Tr. 69:8-14; and Dr. Joel Howell, Director of the Robert Wood Johnson Clinical Scholars Program at the University of Michigan, testified in rebuttal as an expert in evaluation of medical research, Tr. 2673:13-25.

New York Testimony on Abortion Methods

As the undisputed testimony showed and the New York district court found, approximately 90% of all abortions occur during the first trimester of pregnancy, and approximately 10% during the second. *NAF*, 330 F. Supp. 2d at 464. During the second trimester (which begins at thirteen to fourteen weeks from the first day of the woman's last menstrual period before she became pregnant ("LMP")), approximately 95% of abortions are performed using the D&E method. Tr. 779:7-8, 802:9-14 (Westhoff).

D&E consists of dilating the cervix and evacuating the uterus. Tr. 1552:19-21 (Chasen). Both Plaintiffs' and the government's witnesses testified that the physician's goal in any D&E is to empty the uterus in the safest way possible for the woman. *See e.g.*, Tr. 2701:5-2703:13 (government's expert Bowes); Tr. 1363:21-1364:1 (Weiss).

In a D&E, the physician first dilates and softens the cervix so that the uterus can be safely evacuated. *NAF*, 330 F. Supp. 2d at 464 (quoting trial testimony). To achieve adequate dilation, physicians typically place osmotic dilators in the cervix, which expand slowly as they absorb moisture from the cervix, thereby gradually opening it. *Id.* at 464-65. Once dilation is adequate, the physician inserts instruments or his or her fingers through the dilated cervix and into the uterus, to grasp the fetus. The physician then uses traction (*i.e.*, pulling) to remove the fetus from the uterus. Tr. 786:22-787:18 (Westhoff).

As the New York record demonstrates, during a D&E, the fetus may be removed intact or in parts. Both parties' experts testified that physicians performing D&Es seek to minimize the number of times they insert instruments into the uterus. They therefore try to remove as much of the fetus as possible with each pass of an instrument. *See* Tr. 1849:23-1850:3 (government's expert Lockwood); Tr. 2709:6-2710:6 (government's expert Bowes); Tr. 794:11-16 (Westhoff); Tr. 479:18-23 (Johnson). In some cases, depending on factors such as the degree of cervical dilation achieved, the tensile strength of the fetal tissue, and the position of the

fetus, the physician is able to remove the fetus intact or relatively intact with the first pass of instruments.[7] *See* Tr. 1572:19-1574:4 (Chasen); *see also* Tr. 791:17-792:6, 786:22-787:10 (Westhoff); Tr. 2696:4-10 (government's expert Bowes). The experts in New York testified, however, that despite attempts to remove the fetus as intact as possible, the process often results in removal of the fetus in parts, with the physician reinserting instruments—and extracting as much of the fetus as possible with each instrument pass—until the evacuation is complete.[8] *See* Tr. 786:22-787:10 (Westhoff); Tr. 1454:14-19 (Paul); Tr. 1503:11-24 (Creinin); Tr. 1573:23-1574:4 (Chasen).

A variety of terms—such as "intact D&E" or "D&X"—were used throughout the New York trial to describe second-trimester surgical abortions in which the fetus is removed intact or largely intact. Regardless of the term employed, the New York experts testified that such a procedure is "a variation of . . . D&E." Tr. 1065:6 (Frederiksen); *see also* Tr. 212:4-6, 231:23 (Grunebaum); Tr. 1450:8-10 (Paul); Tr. 665:22-666:3 (Hammond).[9]

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[7] The testimony in New York showed that physicians do not use a different dilation protocol to achieve an intact extraction. Rather, the same standard protocol may result in more dilation with a given patient, increasing the possibility of a relatively intact extraction. *See* Tr. 597:10-14 (Hammond) (physicians "do nothing differently before [their] intact procedures"); *see also PPFA*, 320 F. Supp. 2d at 965 (physicians "cannot . . . ascertain[]" the "potential for a largely intact removal" until the dilators are removed and "the surgical procedure has already begun").

[8] The fetal skull is the largest part of the normally developed fetus and is typically too large to pass through the cervix during a D&E. As a result, whether the fetus is dismembered or removed intact, the physician must reduce the size of the skull to complete the delivery. *See* Tr. 796:11-12, 797:25-798:14 (Westhoff); Tr. 643:8-11 (Hammond); Tr. 1573:7-13 (Chasen).

[9] The Act's findings, and the government, attempt to define D&Es with intact removal as if they were an entirely distinct procedure from D&Es involving dismemberment. However, the record evidence in New York showed that physicians who perform them "consider all D&E's [sic] part and parcel of the same procedure." Tr. 597:10-15 (Hammond); *see also PPFA*, 320 F. Supp. 2d at 966 ("[t]he only physicians who referred

The testimony in New York showed that virtually all of the remaining second-trimester procedures (five percent) are performed using the induction method. In an induction abortion, which can last anywhere from fewer than twelve hours to more than forty-eight hours, pre-term labor is initiated with medication, the cervix dilates, and the fetus is generally expelled through the labor process. *NAF*, 330 F. Supp. 2d at 467. In some induction abortions, however, the physician must intervene with surgical steps to complete the evacuation as safely as possible for the woman. When this happens, the physician uses the surgical techniques of D&E to complete the procedure. *Id.* at 468-69.

The uncontested evidence presented in the New York trial established that any D&E or induction—whether used to induce abortion or to treat pregnancy loss (sometimes called "miscarriage")—may fall within the definition of "partial-birth abortion" contained in the Act. *See* Tr. 298:21-299:8 (Grunebaum); 639:2-644:17 (Hammond); 854:3-862:20 (Westhoff); *see also* Tr. 1877:22-1878:18 (government's expert Lockwood).

The remaining procedures for pregnancy termination in the second trimester, hysterectomy (removal of the uterus) and hysterotomy (essentially a pre-term cesarean section), are rarely used to terminate pregnancies because of their inherent risks and consequences for future reproduction. They nonetheless remain legal and can be used in those unusual circumstances in which they may be the safest method for a given patient with a critical medical condition. *NAF*, 330 F. Supp. 2d at 467 (quoting trial testimony).

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to" intact procedures "as . . . separate . . . were witnesses who had never performed the[m]"). Despite the fact that both variants are used at the same point in pregnancy, the government seeks to stigmatize one as aberrant and to embrace the other as "standard." Pet. Br. 11.

ARGUMENT

LIKE THE TWO RECORDS BEFORE THIS COURT, THE NEW YORK RECORD SHOWS THE IMPORTANCE OF INTACT D&E TO WOMEN'S HEALTH.

The extensive evidence presented in New York is entirely consistent with that presented in the Nebraska and California cases under review. The New York court heard "more evidence during its trial than Congress heard over the span of eight years," including testimony from a greater number of physicians on the safety of D&E involving intact removal. *NAF*, 330 F. Supp. 2d at 482. In addition to Plaintiffs' highly credentialed experts, who testified to the significant safety advantages of intact D&E, several of the government's experts acknowledged that such procedures may reduce the risk of dire complications and provide safety advantages for some patients. *Id.* at 461-73. That evidence demonstrated that intact D&E is well within the standard of care; that it is becoming ever more widely used as greater numbers of physicians learn this approach to D&E and read about its benefits in the medical literature; and that a ban on its use would harm women's health.

Accordingly, like the courts whose decisions are under review, the New York trial court found that "[t]here is no consensus that D&X is never medically necessary, but there is a significant body of medical opinion that holds the contrary." *Id.* at 482. This conclusion, affirmed by the Second Circuit, places the New York decision in an unbroken line that has struck down laws banning intact D&E since this Court's decision in *Stenberg* v. *Carhart*, 530 U.S. 914 (2000).

A. On the Basis of Abundant Evidence, the New York Court Rejected Congress's Demonstrably Incorrect Findings.

Like the courts in Nebraska and California, the New York court concluded that Congress's findings were belied by both the congressional record itself and abundant trial evidence. Having observed that "[e]ven the government's own experts disagreed with almost all of Congress's factual

findings," *NAF*, 330 F. Supp. 2d at 482, the court held that those findings cannot satisfy even the highly deferential standard the government urged. The court, that is, found that the findings do not even reflect "reasonable inferences based on substantial evidence." *Turner Broad. Sys., Inc.* v. *FCC*, 512 U.S. 622, 666 (1994).

1. Contrary to Congress's Findings, the New York Record Established That There is No Medical Consensus Against Intact D&E.

The New York court rejected Congress's finding that there is a "consensus" that D&E with intact removal "is never medically necessary and should be prohibited." Act § 2(1). In fact, as the court found, "[t]he congressional record itself undermines this finding." *NAF*, 330 F. Supp. 2d at 488. The court likewise rejected the related findings that Congress made in an attempt to circumvent *Stenberg*. As the court observed, "[t]he face of the congressional record [itself] rebuts" Congress's finding "that D & X is a disfavored medical procedure that is not embraced by the medical community, 'particularly among physicians who routinely perform other abortion procedures.'" *Id.* at 490 (quoting Act § 2(2) and citing *id.* §§ 13, 14(O)); *see also id.* §§ 13, 14(O) (procedure "lies outside the standard of medical care" and "is unrecognized as a valid abortion procedure by the mainstream medical community"). The court found that:

> First, the [congressional] record includes the statements of nine associations, including ACOG and APHA, which opposed the ban because they believe that the procedure offers safety advantages .... Second, the congressional record contains letters from numerous individual physicians—whose practices include performing abortions—stating that maternal health would be jeopardized under the Act. Third, medical textbooks, which were included in the congressional record, discuss D&X as a medically recognized means to terminate a pregnancy.

330 F. Supp. 2d at 490 (citations omitted); *see also Hearing on H.R. 760: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 108th Cong. 186-88 (2003); *Partial-Birth Abortion: The Truth: Joint Hearing on S.6 and H.R. 929 Before the Senate Comm. on the Judiciary and the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 105th Cong. 23-35 (1997) (medically-based opposition to Act of Plaintiff NAF and of Planned Parenthood, representing physicians who perform an array of abortion procedures).

In addition to the congressional record, the New York court found that the "[t]estimony adduced at trial bolsters this conclusion" that Congress was "unreasonable to conclude that a consensus within the medical community" opposes intact D&E. 330 F. Supp. 2d at 489. That testimony includes the concessions of the government's own witnesses that no such consensus exists. *Id.* at 443; *see also* Tr. 2700:2-11, 2714:14-23 (government's expert Bowes).

Abundant trial evidence likewise disproved Congress's other "findings." For example, Congress asserted that intact D&E was not taught at any medical schools, Act § 2(14)(B). Yet, "[t]estimony at trial adduced that, contrary to Congress's finding, the procedure is taught at leading medical schools," *NAF*, 330 F. Supp. 2d at 490, including, as experts for both sides testified, Columbia, Cornell, New York University, Northwestern, and Albert Einstein College of Medicine. *Id.* at 479, 490 (citing testimony of, *inter alia*, government's experts Lockwood and Sprang). Dr. Lockwood, a witness for the government and Chair of the obstetrics and gynecology department at Yale Medical School, testified that intact D&E was taught under his chairmanship at New York University, Tr. 1794:4-1795:8, and that he "intends to develop a program at Yale which would teach the procedure." *NAF*, 330 F. Supp. 2d at 479. Currently, at least six additional medical schools, including Yale, provide instruction on this surgical technique. The record likewise reflects that authoritative medical textbooks discuss intact D&E and its safety benefits. *See id.* at 471

(citing A CLINICIAN'S GUIDE TO MEDICAL & SURGICAL ABORTION 136 (Maureen Paul *et al.*, eds. 1999)); *see also* WILLIAMS OBSTETRICS 243 (F. Gary Cunningham *et al.* eds., 22d ed. 2005); Phillip G. Stubblefield, *First and Second Trimester Abortion*, in GYNECOLOGIC, OBSTETRIC AND RELATED SURGERY 1033, 1043 (David H. Nichols & Daniel L. Clarke-Pearson eds. 2d ed. 2000).

The New York record similarly refuted Congress's claim that intact D&E has not been the subject of peer-reviewed studies and articles. *See* Act § 2(14)(B). The record includes the testimony of *amicus* Dr. Stephen Chasen—Director of High-Risk Obstetrics at New York Presbyterian-New York Weill-Cornell Medical Center, where he also teaches—as well as the first of two articles Dr. Chasen has published in an authoritative peer-reviewed journal comparing D&E involving intact removal to D&E involving dismemberment. *See* Stephen T. Chasen *et al.*, *Obstetric outcomes after surgical abortion at ≥ 20 weeks' gestation*, 193 Am. J. of Obstetrics & Gynecology, 1161-64 (2005); Stephen T. Chasen *et al.*, *Dilation and evacuation at ≥ 20 weeks: Comparison of operative techniques*, 190 Am. J. of Obstetrics & Gynecology, 1180-83 (2004). *See* discussion *infra* at 18-19. Other peer-reviewed articles also discuss intact D&E and its safety advantages. *See, e.g.*, Phillip G. Stubblefield *et al.*, *Methods for Induced Abortion*, 104 Obstetrics & Gynecology 174-85 (July 2004); David A. Grimes, *The Continuing Need for Late Abortions*, 280 JAMA 747-50 (Aug. 26, 1998).

2. Evidence at the New York Trial Disproved Congress's Findings Regarding the Health Risks of Intact D&E.

The New York trial court correctly concluded that the evidence presented at trial refuted Congress's assertion that "overwhelming evidence" demonstrates that D&E involving intact removal presents serious increased risks to women. Act § 2(14)(A). The court concluded, for example, that "[e]xperts for both sides labeled . . . inaccurate" Congress's finding that intact removal increases the risk of uterine rup-

ture, abruption, amniotic fluid embolus, and trauma to the uterus. *NAF*, 330 F. Supp. 2d at 489; *see also, e.g.*, Tr. 2419:3-2420:13 (government's expert Clark); Tr. 2706:19-2707:17 (government's expert Bowes); Tr. 1831:18-1832:10 (government's expert Lockwood). Similarly, the trial court found that experts for both sides agreed that intact D&E "does not involve the capricious and erratic use of instruments," thus undercutting Congress's finding that the procedure poses an increased risk of maternal laceration and bleeding. 330 F. Supp. 2d at 489-90. The government's own experts agreed at the New York trial that there is simply no evidence that performing a D&E with intact removal poses greater safety risks than performing one involving dismemberment. *See* Tr. 2706:19-2707:17 (government's expert Bowes); Tr. 1880:2-5, 1880:23-1881:4; 1881:5-7 (government's expert Lockwood); Tr. 2151:23-25 (government's expert Sprang).[10]

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[10] Evidence presented at the New York trial also contradicted Congress's finding that removing the fetus intact in a D&E increases a woman's risk of cervical incompetence, which can lead to pre-term birth in subsequent pregnancies. *See NAF*, 330 F. Supp. 2d at 467 (citing Westhoff). The district court incorrectly suggested that Dr. Chasen's original study indicates an increased risk of subsequent pre-term birth: as experts from both sides explained, this difference between the two groups—women who had received intact D&Es and women who had received D&Es with more dismemberment—was statistically insignificant because there were so few patients in this part of the study. 330 F. Supp. 2d at 467; Tr. 1629:15-1631:9 (Chasen); Tr. 2679:18-2680:11 (Howell); Tr. 2425:1-25, 2429:16-2430:13 (government's expert Clark) (conceding that "one can reach no conclusions" from the Chasen study about the procedure's impact on risk of subsequent pre-term birth). No less important, as the government's experts conceded, women in the intact group in the study had *pre-existing* risk factors for pre-term delivery to a far greater degree than did women in the dismemberment group. *See* Chasen *et al.*, *Dilation and evacuation at ≥20 weeks: Comparison of operative techniques*, 190 Am. J. of Obstetrics & Gynecology, 1180, 1183 (2004); *see also* Tr. 2412:8-11, 2427:12-2429:1 (government's expert Clark); Tr. 2614:15-2615:6 (government's expert Cook). Indeed, each of the two women from the intact group who delivered a subsequent pregnancy pre-term had undergone the abortion in the study specifically because she had begun to lose that earlier pregnancy through premature rupture of the membranes or prema-

B. The New York Trial Record, Like the Nebraska and California Records, Amply Demonstrates the Safety Advantages of Intact D&E.

The New York trial record supports the safety advantages of intact D&E based on three demonstrated facts: (1) D&Es of all variations have safety advantages over induction abortions, (2) D&Es with intact removal have safety advantages over D&Es with dismemberment, and (3) these safety advantages are especially important for women who are particularly vulnerable to catastrophic complications by virtue of their already compromised medical states.

First, it is uncontested that prohibiting D&Es in general would endanger women's health. At the New York trial, all parties' experts agreed that, while D&E and induction are both extremely safe procedures, D&E is generally safer than induction at certain stages of pregnancy. *NAF*, 330 F. Supp. 2d at 467-68 (citing testimony of government's experts Lockwood, Sprang, and Clark, and Plaintiffs' expert Frederiksen). It was also undisputed that for numerous women, induction is dramatically less safe than D&E. These patients include, for example, women at high risk of uterine rupture during an induction, due to prior scarring from procedures such as high (also known as "classical") cesarean sections or from the surgical removal of uterine fibroids. *See* Tr. 1817:24-1818:8, 1818:19-22 (government's expert Lockwood); Tr. 2358:22-2359:17, 2407:21-2408:7, 2408:18-24 (government's expert Clark); Tr. 1584:22-1585:9 (Chasen); Tr. 1080:1-4 (Frederiksen); Tr. 223:25-224:16 (Grunebaum).

Second, the evidence presented in New York showed that numerous physicians believe that, among D&E vari-

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ture cervical dilation. Both those events are known risk factors for preterm delivery in future pregnancies. *See* Chasen *et al.*, *Dilation and evacuation at ≥ 20 weeks: Comparison of operative techniques*, at 1183. For this reason, the California and Nebraska courts both found that the Chasen study does *not* support the claim that intact D&E may increase the risk of subsequent pre-term birth. *See Carhart*, 331 F. Supp. 2d at 1022; *PPFA*, 320 F. Supp. 2d at 1001.

ants, D&E involving intact removal may be the *safest* way—although not the only way—to terminate a pregnancy in the second trimester. *See, e.g.*, Tr. 1588:23-1589:5, 1632:3-1633:4 (Chasen); Tr. 563:15-23 (Hammond); Tr. 824:12-17, 840:4-12, 841:20-22 (Westhoff); Tr. 1439:1-6, 1445:10-21, 1451:9-1452:9 (Paul); Tr. 1321:10-16, 1338:1-11, 1345:23-1346:2, 1421:2-12 (Weiss); Tr. 453:19-21 (Johnson); Tr. 1053:7-20, 1161:21-24 (Frederiksen); Tr. 1503:25-1504:2 (Creinin). Even the government's experts agreed that there are intuitive advantages to intact removal. Tr. 1828:4-14 (government's expert Lockwood); Tr. 2708:19-22, 2709:6-2710:6 (government's expert Bowes). Indeed, government witness Dr. Lockwood conceded that, compared to dismembering the fetus, intact removal might carry lower risks of injury to the woman. Tr. 1880:6-8. This is so for several reasons, as the evidence presented in New York showed:

- By reducing the number of times a physician must insert instruments through the cervix and into the uterus, intact removal reduces the risk of what government expert Dr. Lockwood called the most feared complication of D&E with dismemberment—uterine perforation. 330 F. Supp. 2d at 471 (citing testimony of government's experts Lockwood and Cook and of Plaintiffs' experts); Tr. 1765:21-1766:1, 1822:16-1823:1, 1823:14-1824:6 (government's expert Lockwood); Tr. 2548:5-23 (government's expert Cook). The government's experts agreed that it is medically appropriate to attempt to make as few instrument passes as possible, Tr. 1825:12-16 (government's expert Lockwood); Tr. 2708:19-22, 2709:18-2710:6 (government's expert Bowes), and Dr. Lockwood testified that making fewer passes with instruments also reduces the risk of infection. Tr. 1825:9-20 (government's expert Lockwood). Testimony from ACOG (presented by deposition of its representative, Dr. Joanna Cain) showed that ACOG viewed reduced instrumentation as a significant reason why D&E with intact removal may be the best or most appro-

priate abortion method to save the life or preserve the health of a woman. Tr. 185:2-18 (Cain).

- Removing the fetus intact virtually eliminates the risk that fetal tissue will be left in the uterus. Retained tissue increases the likelihood of infection, hemorrhage, and infertility. *NAF*, 330 F. Supp. 2d at 472; Tr. 248:13-249:9 (Grunebaum); Tr. 570:8-571:18 (Hammond); Tr. 824:18-825:7 (Westhoff); Tr. 1045:13-22, 1053:7-20, 1060:8-1064:18 (Frederiksen); Tr. 1322:25-1324:3, 1421:2-12 (Weiss); Tr. 1441:10-16 (Paul); Tr. 1590:21-24, 1593:2-9 (Chasen). The government's expert Dr. Lockwood agreed that intact removal logically lowers the risk of retained tissue. Tr. 1769:3-4.

- D&E with intact removal takes less operating time than D&E with dismemberment, and may thus reduce bleeding, the risk of infection, and exposure to anesthesia. 330 F. Supp. 2d at 472 (citing trial testimony of government's experts Bowes and Lockwood and Plaintiffs' experts Grunebaum, Hammond, Westhoff, Weiss, and Chasen). The government's experts agreed that a shorter procedure time is medically advisable for these reasons. Tr. 1825:21-1826:9 (government's expert Lockwood); Tr. 2709:6-16 (government's expert Bowes).[11]

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[11] Contrary to the New York district court's suggestions and the government's claims here, *see* Pet. Br. 37 n.12, Dr. Chasen's original comparison study of D&E variants does not belie this evidence. While the procedure times for the two study groups was the same, the intact D&E group was, on average, two weeks further along in pregnancy, meaning that their procedure times were expected to be longer than the times for the group that had D&Es with dismemberment. *See* Tr. 1628:13-1629:19, 1634:5-16, 1680:2-6 (Chasen); Tr. 884:17-885:21 (Westhoff); Tr. 289:14-291:14 (Grunebaum). The fact that they were not longer indicates that the intact approach does reduce procedure time for D&E.

- Intact removal is less likely to expose the uterus and cervix to sharp fetal bone and skull fragments. 330 F. Supp. 2d at 471; Tr. 1825:17-20 (government's expert Lockwood); Tr. 447:4:-448:19 (Johnson); Tr. 565:7-566:2, 568:19-570:7, 592:2-9 (Hammond); Tr. 1053:11-18, 1058:10-1059:10 (Frederiksen); Tr. 1330:25-1332:8 (Weiss); Tr. 1590:1-17, 1592:9-15, 1611:11-1612:2 (Chasen); Tr. 793:2-794:5, 824:18-825:2 (Westhoff). The government's experts agreed that cervical laceration and uterine perforation are risks of dismemberment D&E. Tr. 2411:9-12 (government's expert Clark); Tr. 1825:9-20 (government's expert Lockwood); Tr. 2548:5-23 (government's expert Cook). And the evidence showed that sharp fetal fragments are the leading cause of this complication. Tr. 1058:10-23 (Frederiksen).

The New York record also included testimony regarding Dr. Chasen's original study, the first peer-reviewed study specifically comparing dismemberment and intact removal in D&Es. *See* Chasen *et al.*, *Dilation and evacuation at ≥ 20 weeks: Comparison of operative techniques*, 1180-83, *supra* at 13. Experts testified that the study demonstrated that intact removal is at least as safe as, and probably safer than, dismemberment in a D&E. Tr. 1612:22-1614:13, 1625:21-1629:14, 1632:3-1633:4, 1634:3-16, 1679:12-1681:8, 1694:18-1695:16 (Chasen); Tr. 838:18-25, 884:17-885:21 (Westhoff); Tr. 289:14-291:14 (Grunebaum); *Carhart*, 331 F. Supp. 2d at 962 (government's expert "Dr. Lockwood testified that the Chasen study 'suggests [the intact D&E method of abortion is] safe'" (alteration in original)).

The two patient groups in the study—those who had relatively intact procedures at a median gestational age of 23 weeks LMP, and those who had dismemberment procedures at a median gestational age of 21 weeks LMP—experienced comparable bleeding, procedure times, and complication rates (although all of the serious complications occurred in the dismemberment group). Chasen *et al.*, *Dilation and evacuation at ≥ 20 weeks: Comparison of operative tech-*

niques, at 1182-83 *supra* at 13. The fact that the complication rates were comparable was significant because, as Dr. Chasen and other experts testified, the patients in the intact group were at greater risk of complications because they were two weeks further along in pregnancy and the risks of abortion increase as pregnancy advances. Tr. 805:2-7 (Westhoff). Thus, the intact group would have been expected to have *worse* outcomes. Tr. 1625:21-1630:1, 1632:3-1633:4, 1634:3-16, 1679:12-1681:8, 1694:18-1695:16 (Chasen); Tr. 884:17-885:21 (Westhoff); Tr. 289:14-291:14 (Grunebaum). The fact that they did not "provide[s] medical support for the conclusion that intact D&E is a safe, and sometimes necessary, procedure." *PPFA*, 320 F. Supp. 2d at 1034.

Third, the New York record also included abundant evidence that intact removal may be the safest option for women with certain medical conditions who are terminating their pregnancies. In such cases, the benefits described above are particularly important given the patient's already compromised medical state and increased vulnerability to catastrophic complications. These conditions include, for example, being prone to or having infection, *NAF*, 330 F. Supp. 2d at 473; Tr. 1826:16-1827:9 (government's expert Lockwood); experiencing, or being at risk for, chorioamnionitis, a potentially deadly infection of the amniotic fluid and membranes that, among other things, increases the risk of uterine perforation, *NAF*, 330 F. Supp. 2d at 473; Tr. 1825:9-20, 1826:16-1827:20 (government's expert Lockwood); Tr. 588:19-590:7 (Hammond); being otherwise at risk of hemorrhage, *NAF*, 330 F. Supp. 2d at 473 (citing Hammond); having compromised immune systems, *id.*; and being prone to perforation or having uterine scarring, *id.* (citing *inter alia* government's expert Lockwood); Tr. 1335:18-1336:5 (Weiss); *see also* Tr. 1056:14-24 (Frederiksen). In addition, ACOG's expert panel pointed to numerous such conditions that make intact D&E the safest abortion method for certain patients. *See, e.g.*, Tr. 153:10-20, 154:16-23, 158:13-21, 185:2-18 (ACOG representative Cain). In addition to these conditions, there was also testimony in New York that D&E with intact removal could benefit women carrying fetuses with certain

anomalies, such as hydrocephaly (which greatly enlarges the fetal head), *NAF*, 330 F. Supp. 2d at 473 (citing government's and Plaintiffs' experts), and that it may also help in the post-abortion pathological diagnosis of certain fetal conditions. *See id.* (citing Westhoff).

* * *

In sum, there was ample evidence in New York from highly credentialed experts on both sides to support the conclusion that banning intact D&E without a health exception creates "unnecessary risk of tragic health consequences." *Stenberg*, 530 U.S. at 937. The evidence showed that the unique advantages of intact removal—reduction of instrument passes, fetal fragmentation, and procedure time—minimize the likelihood of complications that, while perhaps infrequent in an absolute sense, are potentially catastrophic in the very real cases when they do occur. The potential consequences of these complications include hemorrhage, overwhelming and systemic infection, and infertility. *NAF*, 330 F. Supp. 2d at 471-72; *supra* at 16-18 Such potentially catastrophic complications are no less constitutionally cognizable simply because they are, fortunately, rare.[12]

C. The New York District Court's Characterization of Some of the Evidence Does Not Undermine Its Central Conclusion That Substantial Medical Evidence Supports the Safety Advantages of Intact D&E.

Contrary to the government's suggestion, *see* Pet. Br. 40-41, the New York court did not reject the essential safety benefits on which Plaintiffs' case rested. While the court opined that certain of Plaintiffs' proffered reasons for their belief in the safety advantages of intact D&E were "not credible" or even "false," the court did not so characterize

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[12] This court's precedent offers no support for the suggestion in Chief Judge Walker's Second Circuit concurrence that procedures that reduce such complications offer only "marginal" and constitutionally insignificant benefits. *NAF*, 437 F.3d at 291.

the health benefits described above. Moreover, the court also found that Congress was "unreasonable" in concluding that there is "no credible medical evidence" that intact D&Es offer safety advantages. 330 F. Supp. 2d at 489. In so holding, the court necessarily found that *credible* medical evidence disproved Congress's false "findings."

The New York court did not state that any specific reason Plaintiffs offered in support of the medical advantages of intact procedures was "false" or "not credible." Instead, it merely noted that these advantages were "theoretical" or "hypothetical" because they were based on physician experience, and had not yet been proven by controlled studies—studies this Court has made clear are not necessary to support the need for a health exception.

As this Court held in *Stenberg*, the "absence of controlled medical studies" cannot defeat the need for a health exception. *See* 530 U.S. at 936-37. This Court, and lower courts, have never required that medical benefits be proven through studies as a prerequisite to invalidating bans on abortion procedures. In fact, banning a procedure would perversely preclude such studies ever being conducted. As this Court explained in *Stenberg*, "[m]edical treatments and procedures are often considered appropriate (or inappropriate) in light of *estimated* comparative health risks (and health benefits) in particular cases." *Id.* at 937 (emphasis added); *see also Planned Parenthood* v. *Danforth*, 428 U.S. 52, 77-78 (1976) (invalidating ban on saline abortions despite absence of studies demonstrating comparative benefits of saline versus prostaglandin induction);[13] *Planned Parent-*

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[13] The trial court in *Danforth* heard testimony from two plaintiff-physicians and from four physicians who supported the ban. *See* Brief of John C. Danforth, Attorney General of Missouri, *Danforth*, 428 U.S. 52 (1976) (No. 74-1151, 74-1419), at 58-68; Brief for Planned Parenthood of Central Missouri, David Hall, M.D., and Michael Freiman, M.D., *Danforth*, 428 U.S. 52 (1976), (No. 74-1151, 74-1419), at 123-25; *see also* Brief as *Amici Curiae* for Planned Parenthood Federation of America, Inc., Association of Planned Parenthood Physicians, Inc. and Certain Medical School

hood v. *Taft*, 444 F.3d 502, 513 (6th Cir. 2006) (invalidating ban on alternative protocol for administering abortion drug after concluding that "studies are not necessary where there is expert testimony that a restricted procedure is safer than the alternatives"); *Wynn* v. *Scott*, 449 F. Supp. 1302, 1326 (N.D. Ill. 1978) (invalidating saline abortion ban on the basis of physician affidavits and drug manufacturer's description without studies in the record).

Evidence presented in the New York trial explained why requiring definitive controlled studies of intact D&E at this point would be unreasonable and at odds with the way medical innovations typically develop. Dr. Sherwin Nuland, formerly a practicing surgeon and now a professor of bioethics and medical history at Yale Medical School, testified that innovative surgical techniques such as intact D&E arise through a "process of evolution," proceeding from the initial flash of insight, then spreading within the profession by word of mouth, and moving gradually to scientific study with retrospective peer-reviewed reports and case studies (the current status of research relating to intact D&E), and only much later (and only if possible) to controlled experimentation. Tr. 69:21-73:2. Controlled studies require a sufficient sample size, which might be difficult to achieve here given the relative infrequency of second-trimester abortion by any method, and, in particular, the relative rarity of complications. *Id.* at 79:25-80:7. This limitation exists for any study of second-trimester abortion. *See, e.g.*, Tr. 1822:12-15 (government's expert Lockwood).[14] Given this limitation, the New York court's criticism of Plaintiffs' failure to provide controlled studies demonstrating that D&E with intact re-

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Deans, Professors and Individual Physicians, *Danforth*, 428 U.S. 52 (1976), (No. 74-1151, 74-1419), at Point II.

[14] For example, the government's expert Dr. Lockwood was unable to identify any randomized, controlled studies supporting his opinion that there may be safety advantages to induction abortion over surgical abortion after 20 weeks LMP.

moval lessens the risk of already-rare complications is misplaced.

The New York court also inappropriately relied on the views of a single government witness, Dr. Clark, to discredit Plaintiffs' experts' testimony supporting the safety advantages of intact D&E. Dr. Clark, who admitted to being only moderately skilled in performing abortions, Tr. 2399:19-24, contended that certain specific health conditions would not "necessitate" a D&E with intact removal. However, the conditions on which his testimony focused were not among those Plaintiffs had offered to support the greater safety of intact D&E. Instead, they included conditions Plaintiffs had offered as examples of why women obtain second-trimester abortions generally, or of why surgical D&E offers advantages over induction abortion.[15] Even the government's own witness, Dr. Lockwood, agreed that there may be advantages to intact removal over dismemberment in some cases. Dr. Lockwood specifically noted such potential advantages for women suffering from chorioamnionitis, a potentially deadly infection of the amniotic fluid and membranes that, among other things, increases the risk of uterine perforation. Tr. 1826:16-1827:18 (government's expert Lockwood). Dr. Clark's testimony notwithstanding, the New York court clearly recognized that the evidence demonstrated "a division of medical opinion" regarding the advantages of intact D&E for women with certain health conditions, such as "uterine scarring, placenta previa, preeclampsia, bleeding disorders, and infections"—a division that requires an exception to preserve women's health. *NAF*, 330 F. Supp. 2d at 481.

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[15] *See e.g.*, Tr. 1017:11-21 (Westhoff) (peripartum cardiomyopathy as example of condition that prompts some women to terminate pregnancy in the second trimester); Tr. 594:10-17 (Hammond) (Von Willebran's disease as example of condition that makes surgical approach (*i.e.*, D&E) far preferable to induction abortion); Tr. 2332:20-2334:5; 2349:24-2350:14 (government's expert Clark opining that that neither peripartum cardiomyopathy nor Von Willebran's disease necessitates intact D&E).

Finally, the Nebraska and California courts, both of which heard the same evidence, were untroubled by the absence of controlled studies or the consequently "theoretical" nature of the proffered health advantages of intact D&E, which advantages they found compelling. After hearing the testimony of substantially the same witnesses who testified in New York, both the California and Nebraska courts "f[ou]nd[] that intact D&E is in fact the safest medical option . . . in some circumstances and is significantly safer than induction, hysterotomy, or hysterectomy for terminating a second trimester pregnancy, and under certain circumstances, also significantly safer than D&E by disarticulation." *PPFA*, 320 F. Supp. 2d at 1002; *see also Carhart*, 331 F. Supp. 2d at 1018. Both courts also found that Plaintiffs' witnesses' "expertise in recommending and performing D&E and intact D&Es is unassailable . . . ." *PPFA*, 320 F. Supp. 2d at 1001 ("[T]he court accepts their testimony over that of the government witnesses, who . . . were not qualified to testify as experts on the practice."); *see also Carhart*, 331 F. Supp. 2d at 1025 ("In order to find that" D&E with intact removal does *not* bring safety advantages, "one would have to dismiss the views of highly trained and very experienced physicians . . . who have detailed knowledge of the surgical methods under discussion [and] would have to accept the contrary views of doctors . . . who have virtually no experience with abortions. Choosing . . . this nadir of inexperience . . . would be plainly unreasonable.") These contrary findings cast serious doubt on the New York court's view of some aspects of the evidence.

CONCLUSION

For the reasons set forth above, and in the Brief for the Respondents, the Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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AUGUST 2006

APPENDIX

APPENDIX

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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03 Civ. 8695 (RCC)

NATIONAL ABORTION FEDERATION, MARK I. EVANS, M.D., CAROLYN WESTHOFF, M.D., MSC; CASSING HAMMOND, M.D., MARK HELLER, M.D., TIMOTHY R.B. JOHNSON, M.D., STEPHEN CHASEN, M.D., GERSON WEISS, M.D., ON BEHALF OF THEMSELVES AND THEIR PATIENTS,

Petitioners,

V.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE U.S., ALONG WITH HIS OFFICERS, AGENTS, SERVANT, EMPLOYEES, AND SUCCESSORS IN OFFICE,

Defendants.

New York, N.Y.
Before:
HON. RICHARD CONWAY CASEY
District Judge

TRIAL TRANSCRIPT EXCERPTS

MARCH 29, 2004

[69:8-14] (Nuland)

MS. WIGMORE: Your Honor, I think we would be comfortable in offering him as an expert in the evolution of surgical procedures, if counsel for the defense has no objection.

MR. LANE: We have no objection.

THE COURT: Their having no objection, he will be acknowledged as an expert in that limited field.

[69:21-73:2] (Nuland)

Q. Have you formed an opinion regarding how surgical procedures change and develop?

A. Yes.

Q. What is your opinion?

A. Surgical procedures by their very nature historically and [70] currently come to be by a process of evolution. What essentially happens is that based on the technology of the particular era in which surgeons are working, one or two or several begin to conceive that a certain procedure might make some sense. It might make sense physiologically, might make sense therapeutically, might make sense technically, and might perhaps be done with a significant degree of safety.

They begin doing those procedures primarily, historically, on human beings rather than animals. They may test the technique itself on animals, but the important thing is that the physiological results can only be tested on humans. So that will be done.

When word gets out by word of mouth, medical meetings, perhaps a letter, perhaps a phone call, perhaps a very preliminary report in a journal, others will come to watch what they are doing, will meet with them at medical meetings, decide whether these procedures have the merit that the originators claim, and then go back to their own institutions and do those things.

Ordinarily, it is customary to keep scrupulous records of the way these new procedures are being done so that in time, when there is a sufficient number of them to judge whether they have true value and are truly safe, in time there will be a publication.

Q. Doctor, can you give us any examples of surgical techniques [71] that have evolved in the manner you have described.

A. Virtually every surgical technique has evolved precisely that way. We can take something as large as cardiac surgery in general, but we don't we restrict it to open-heart

surgery, which I had the opportunity to be involved with at the very beginning, so that I can speak not only as an observer but as a participant.

Q. Can you describe for us how that developed.

A. The notion had long been about that if one could simply prevent blood from getting into the heart, certain diseased parts of the heart, whether they were congenital disease or acquired disease, could be treated. A valve, for example, could be repaired or a hole between the two sides of the heart could be closed. But for that to happen, it was necessary that the heart be emptied of blood, then one could open it and do what was needed.

Of course, for that to happen, a big piece of technology was required. Someone had to invent and build what is called a heart-lung machine, a machine that could both pump the blood and oxygenate it at the same time, so that one could remove the blood from the body before it got to the heart, then return it beyond the anatomical point where the heart is and pump it at the same time.

That took many years in the development. Actually, there is one single person who eventually developed that [72] technology, a man named John Gibbon in Philadelphia. His progress was watched by a lot of others. When that machine was satisfactorily conceived and built and he had operated on a few patients, others began to engineer their own modifications of that equipment, go back to their own institutions, and operate on patients.

Some of those patients had been operated on before the machine was generally available. With so-called cross-circulation techniques, you would use another person's heart to pump the blood, another person's lungs to oxygenate it. But essentially what we were really waiting for was this heart-lung machine.

So Gibbon creates it, engineers it, designs it, and everybody copies it. I well remember, as a young fellow in training, a fellow in the cardiac laboratory at that time, visiting other institutions to watch their innovations, before we in

our institution—actually I can tell you the date, it was December 8, 1956—finally went ahead and did our first procedure.

At that point there were short papers—well, there were also long papers, but there were short groups, rather small groups of patients that had been operated on at different centers. The primary center at that time was the University of Minnesota under the leadership of pioneers in this field.

THE COURT: Under who?

[73] THE WITNESS: The leadership of certain pioneers in the field.

[79:25-80:7] (Nuland)

Q. In your opinion, would it be reasonable to require a controlled study demonstrating the safety of a surgical technique before allowing that technique to be widely used on human patients?

A. I consider that a contradiction in terms, because how can in surgery a controlled study be done unless there have been a statistically significant number of people who have undergone that procedure?

[153:10-20] (Cain)

"Q. What did the tax force discuss with respect to safety?

"A. Numerous examples were raised by the members of the task force regarding different procedures and specific cases and issues of safety. For example, in GYN oncology the most pertinent example would be triploidy, which is a form of cancer of the placenta often diagnosed in the second trimester with severe preeclampsia. In that case, the least amount of instrumentation possible of the uterine wall is desirable. So it is much safer for the woman to have an intact D&X to remove the pregnancy. So multiple issues were used to explore issues of safety at the time and in comparison to other procedures.

[154:16-23] (Cain)

"Q. Well, if you want to look at Exhibit 7, I'll go a little above that, 'Terminating a pregnancy is indicated in some

circumstances to save the life or preserve the health of the mother.' This was obviously a conclusion of the select panel, is that correct?

"A. That is correct, and we could identify numerous circumstances in which this might be the best procedure for that. Rare, but still numerous.

[158:13-21] (Cain)

"Q. Are you aware of any analysis or study—let's strike that and say, are you aware of any study which supports the conclusion that intact D&X may be the best or most appropriate procedure in certain circumstances?

"A. I'm not aware of a study. I am well aware of multiple circumstances that an expert panel could identify at the time of the task force, where it was clearly the best choice, including in my field, where the other options led to a higher likelihood of death or recurrence of disease.

[185:2-18] (Cain)

"Q. Okay. And what are some aspects of the D&X procedure that might lead a physician to conclude that D&X is the best or most appropriate abortion procedure to save the life or preserve the health of a woman?

"A. One of the elements that came up among the different and numerous examples was the decreased instrumentation and ability to preserve relatively intact fetus for evaluation, particularly for some genetic-based congenital anomalies.

"Q. Why would less instrumentation be beneficial?

"A. It depends on the circumstance. In the circumstance of septic abortions, any increase in instrumentation might increase the ability of bacteria to enter the blood stream.

In the case of tropoblastic disease, increased instrumentation is likely to transport tropoblastic disease, which is a form of cancer, to other areas such as the lung.

MARCH 30, 2004

[210:8-213:12] (Grunebaum)

Q. Approximately how many abortions have you performed throughout your career?

A. I started with my medical school in 1968, and attended abortions throughout my medical school and after I finished medical school. So it's about 36 years that I have been doing them, probably about a thousand abortions just as a ballpark. But it is difficult to be very precise.

Q. Of the abortions that you perform in your current practice, approximately what percentage of those are abortions regarding wanted pregnancies?

A. The majority of the abortions that I perform in my practice over the last three years are wanted pregnancies, probably well over 95 percent.

Q. What types of abortions have you performed?

A. I have performed different kinds of abortions. We just described a dilatation and curettage, which is the form of abortion done in the first trimester. That procedure becomes more dangerous as pregnancy progresses, usually after 12 weeks. [211] At that time the options for abortions at that point are usually induction abortions or an abortion called D&E, dilatation and evacuation.

Q. What is an induction abortion?

A. An induction abortion is a type of abortion where labor is being induced, and after the woman has gone through a period of labor the cervix dilates and the fetus and the placenta are being expelled.

Q. Doctor, you have used the term "die-latation," "dilatation." What does that refer to?

A. "Dilatation" stands for opening. In the case of the cervix, it is the opening of the cervix by different means.

Q. Is that ever referred to as "dilation"?

A. Yes.

Q. You mentioned that you perform dilation and evacuation, or D&E's. What are those procedures?

A. A D&E is a form of abortion which is usually done in the second trimester of the pregnancy, which usually begins

around 13 to 14 weeks of the pregnancy. In a D&E, as the first word refers, the cervix is being dilated. What we do now days is we dilate the cervix with small laminaria, we call them, small sticks about a couple of millimeters thick and probably an inch or so long, which we insert into the cervix and leave in the cervix overnight. And sometimes we repeat that procedure the next day.

[212] Q. Are you familiar with the term "intact D&E"?

A. Yes, I am.

Q. What is an intact D&E?

A. As I explained before, D&E is a form of a termination of a pregnancy, an abortion, in the second trimester. The intact D&E is one version how to perform a D&E.

Q. How does that version proceed?

A. In an intact D&E the fetus is removed intact, as the word says. As compared to the other version of the D&E, where the fetus is removed in portions, and the medical term for that is dismemberment".

Q. Dr. Grunebaum, have you performed intact D&E's?

A. Yes, I did.

Q. How did you learn to perform intact D&E's?

A. I saw my first intact D&E's shortly after I arrived at New York Hospital, I believe in the year 2001, when I first saw them. And I learned them in the year 2002.

Q. Is New York Hospital affiliated with New York-Presbyterian Hospital?

A. It is one hospital system, but there are two hospitals that have merged several years back. One is called Presbyterian, the other one is called New York Hospital.

Q. Is New York Hospital affiliated with any medical school?

A. Yes, it is.

Q. With what medical school?

[213] A. Cornell.

Q. Did you receive training in the intact D&E procedure while you were working at Cornell?

A. Yes, I did.

Q. Approximately how many D&Es have you performed since joining the faculty at New York Presbyterian hospital?

A. I have performed or performed myself approximately 15 to 20 D&E's.

Q. 15 to 20 intact?

A. Intact D&E's, correct.

Q. How many D&E's of all types have you performed?

A. Approximately 100.

[223:25-224:16] (Grunebaum)

Q. Doctor, do you have an opinion as to whether D&E offers any [224] safety advantages over induction?

A. Yes: It does.

Q. What are those advantages?

A. Let me first start with contraindications for induction termination of pregnancy. The contraindications for induction termination of pregnancy include a prior scar in the uterus, specifically if the scar is from what we call a classical Cesarean section, is if a woman in a pregnancy has had a classical Cesarean section.

It is called "classical" because that is the first form of Cesarean section, which we started to do approximately 150 years ago. That is an incision in the uterus which is vertical in the top of the uterus. The reason why we cannot do an induction in those women is because a vertical uterine incision is more likely to rupture when a woman goes into labor. And if it ruptures, she can die, bleed out.

[231:23] (Grunebaum)

A. The intact D&E is just one variation of the D&E per se.

[235:18-23] (Grunebaum)

Q. What are those advantages, Doctor?

A. The major advantage that you really don't have to use much instruments. Every time you place an instrument into the uterus, you increase the risk of perforating the uterus.

It is always easier in most or in many medical procedures to remove something you want to remove in an intact way.

[248:13-249:9] (Grunebaum)

Q. Are there any other advantages of intact D&E over dismemberment D&E?

A. Yes. When you break off portions of the fetus you need to ensure that at the end of the procedure all portions have been removed from the uterus.

The reason why that is important is that if you leave anything behind it increases the risk of an infection. You want to ensure at the end of the procedure one of the most important things you do at the end of a, as a dismemberment D&E proceeds and that's actually the part which takes the longest, is to ensure that even the small portions are being removed.

So, you need to go in again and again and again with instruments to make sure that all of these portions are removed **[249]** to decrease the risk of infection and of potential risk of bleeding because retained fetal portions can lead to infection and can lead to bleeding. And, at its worse, they can lead to a woman's infertility.

So that actually, that portion of ensuring completeness with the dismemberment D&E takes up a good portion of the procedure.

And then, after you finish with that part you need to remove the placenta too.

[289:14-291:14] (Grunebaum)

Q. Dr. Grunebaum, are you aware of any studies comparing the relative safety of intact D&E with dismemberment D&E?

A. Yes, I am.

Q. Which study are you aware of?

A. There is a study about to be published with Dr. Chasen as the lead author, I believe.

Q. Could you please describe for us that study generally.

A. That study in general looked retrospectively at women who underwent dilatation and evacuation for termination of pregnancy. It then compared the dismemberment variant to the intact D&E variant.

Q. When you say the study looked retrospectively, what do you [290] mean?

A. Retrospectively is you identify people who undergo a certain procedure or who are under certain situations. Then you abstract information from those medical records and then you compare them with each other.

Q. In the course of your medical practice, have you relied on retrospective studies?

A. All the time.

Q. What were the results of Dr. Chasen's study regarding the comparison of intact D&E and dismemberment D&E?

A. I can give you the general gist. My understanding from the study is that both forms of D&E are safe.

Q. What, if any, impact does Dr. Chasen's study have on your opinion concerning the relative safety of intact D&E and D&E involving dismemberment?

A. It confirms what I said previously, that the intact D&E is as safe or even safer than the dismemberment D&E.

Q. Did Dr. Chasen's study conclude that there was any difference in complication rates for D&E versus intact D&E?

A. Not that I can recall.

Q. What is your basis for concluding that intact D&E offers safety advantages over dismemberment D&E?

A. The study shows that both dismemberment D&E and intact D&E have similar outcomes. But the groups that have been compared in that study are slightly different groups and they differ [291] mostly as to the gestational age of the pregnancies. The average gestation age of the patients in the intact D&E group were slightly more advanced.

THE COURT: Slightly more what?

A. More advanced in pregnancy. I believe they were 23 weeks on average as compared to 21 weeks in the dismemberment D&E.

Q. Do the risks of abortion change at all with the advancement of gestational age?

A. Absolutely. They increase as the gestational age advances. For example, an abortion done at 20 weeks is less risky than that done at 21 weeks, 22 weeks. The reason for that is as we explained before. The fetus is bigger, the placenta is bigger, and the uterus is more distended, so you would expect at a more advanced gestation age more complications.

[298:21-299:8] (Grunebaum)

Q. Dr. Grunebaum, I want to focus your attention now on D&E's involving dismemberment. Do you have any fear of prosecution under the Act if you were to perform a D&E involving dismemberment?

A. Yes, I have.

[299] Q. Why is that the case?

A. Because in a dismemberment procedure, more or less the same as is described under what this Act calls a partial-birth abortion, and I can only read again, "The term 'partial-birth abortion' means an abortion in which a person deliberately performing the abortion deliberately and intentionally vaginally delivers a living fetus." That is what I do in a partial-birth abortion, in a dismemberment D&E also.

[307:17-308:4] (Grunebaum)

Q. Doctor, are you familiar with the term "spontaneous abortion"?

A. Yes. The other word for spontaneous abortion is also a "miscarriage."

Q. What is a miscarriage?

A. A miscarriage is when a woman loses her pregnancy without any act of intervention by anyone.

Q. Do physicians have any role in treating miscarriages?

A. That is one of our major jobs, treating women who have a [308] miscarriage.

Q. Doctor, do you have any fear of prosecution under the Act associated with your treatment of miscarriages?

A. Yes, I do.

[312:1-7] (Grunebaum)

Q. Doctor, in terms of the patients whom you have seen were having spontaneous abortions, do any of them come in when the fetus is still living?

A. Yes.

Q. Have you ever had to perform any medical procedures to manage that process?

A. Yes.

MARCH 31, 2004

[396:4-400:11] (Johnson)

Q. Do you perform abortion procedures, Doctor?

A. I do; yes, sir.

Q. What types of abortion procedures do you do?

A. Currently I am involved, because of my call schedule, only in medical induction procedures.

Q. Do you have privileges to perform surgical procedures?

A. Yes, sir.

Q. And what about your call schedule involves you only in medical induction procedures?

A. Well, currently because of my administrative and daytime duties I take call usually on, on the evening or on weekends. I don't cover the operating rooms or the units during the daytime, which is the time that surgical procedures are carried out.

So, because of that the patients that I see are patients who are admitted for medical induction during my time on call.

Q. Prior to your current schedule and in the past, what types of abortions have you performed?

A. Both medical and surgical abortions, first and second trimester.

Q. And by medical abortions in the second trimester, can you [397] again tell the Court what you mean?

A. I am talking about abortion inductions that are induced using medications, using drugs to induce labor and to cause delivery.

Q. And by surgical procedures in the second trimester, what do you mean by that, sir?

A. Surgical procedures would be operative procedures to perform evaluation of the uterus, so, D&E procedures.

Q. Do you manage spontaneous abortions in the course of your practice?

A. Yes, sir.

Q. How do you do those procedures?

A. Those patients present to the emergency department—generally occasionally to labor and delivery—but to one of our acute triage units, and they're evaluated and then I would participate in their management.

Q. Have you had any training, Dr. Johnson, in abortion procedure?

A. Yes, sir.

Q. Could you describe it for the Court, please?

A. Well, as a resident and as a fellow I received didactic—

THE COURT: Can you tell us where it occurred and when it occurred?

THE WITNESS: Sure. As a resident from 1975 to 1979 we had lectures, [398] directed readings and were involved in abortion procedures at University Hospital. Those were—

THE COURT: That was in Virginia?

THE WITNESS: No, that was at the University of Michigan.

THE COURT: University of Michigan.

THE WITNESS: When I was a resident between '75 and '79; so at that time most of those procedures were mid-

trimester procedures because of the practice in the hospital. I had some experience at Planned Parenthood with first trimester procedures as a resident.

Subsequently, from 1979 to 1981, at Hopkins, I received further training. At the time, from 1979 to 1981, Hopkins had a large abortion research unit and the fellows, including myself, were responsible for managing the complications in that unit, managing the problems in that unit, doing any procedures that needed to be done in that unit at night when we were in-house managing those patients.

Since then I have continued reading the medical literature and attending conferences, attending quality assurance meetings, departmental meetings, and continued to be involved in the education and training of our residents who participate in abortion training in our institution.

Q. You made reference in that answer, Dr. Johnson, to the mid-trimester, I'm not sure we have heard that word, what is [399] the mid-trimester of pregnancy?

A. Considered generally from 12 to 24 weeks, but often in terms of the management we are talking more like 14, 15 weeks until 24 weeks.

Q. And the mid-trimester is synonymous with the second trimester, is that correct?

A. Correct, yes.

Q. Are you familiar with a variation of the D&E procedure known as the intact dilation and evacuation, or intact D&E?

A. Yes, sir.

Q. Have you observed performance of the intact variation of D&E?

A. Yes, sir.

Q. Where did that occur?

A. At affiliated—at training sites that we have a relationship with at our institution.

Q. With respect to—

THE COURT: Where, specifically, Doctor?

THE WITNESS: Well, I'm afraid to identify that place because I'm concerned that my residents and my colleagues who are working there could be identified and targeted as – if that were, became widely known.

MR. HUT: Your Honor, would it be possible at this point perhaps to approach and have the court reporter, if this would be satisfactory to Dr. Johnson, transcribe it only in the [400] presence of the Court and the government, rather than in the full courtroom?

THE COURT: Before we do that, let me understand your concern about the safety of your colleagues.

THE WITNESS: Yes, sir. We have a very small community—

THE COURT: I didn't ask you—

THE WITNESS: I am afraid that my colleagues could be identified if it were known where they were doing their training in their abortions.

THE COURT: All right, I will take it at sidebar.

[421:4-6] (Johnson)

A. Yes. I think that D&E procedure compares favorably to medical induction, especially in the period from 16 to 20 weeks. It has relative safety benefits and other benefits.

[447:4-448:19] (Johnson)

Q. Dr. Johnson, what is uterine perforation?

A. Uterine perforation describes a condition where an instrument or an object goes through the uterine muscle.

Q. What, if any, health risks are associated with uterine perforation, in your judgment?

A. Well, the risks would be either bleeding or infection. Perforation site can lead to bleeding, the bleeding can be either intraperitoneal bleeding or intrauterine vaginal bleeding, infection.

Perforation can either introduce infection into the uterus or introduce infection outside the uterus into the peritoneal cavity.

Those would be the major complications of uterine perforation.

Q. As between the intact variation of D&E and the dismemberment variation, do you have an opinion which, if involve less risk of uterine perforation?

A. Yes.

It would be my opinion that the intact procedure would carry less risk.

Q. What causes the lesser risk in your opinion, Doctor?

A. Well, there are two potential items that can perforate the [448] uterus during a D&E procedure. One would be the instruments themselves and those instruments, with each passage into the uterus have a, have the potential to perforate the uterus so that an intact procedure would reduce the number of passes of the instruments and reduce the risk of perforation with the instruments.

In addition, the dismemberment procedure leads to fetal parts, bony parts, the head, various other body parts that can, themselves, cause perforation.

Long bones, sharp bones can actually perforate the uterus, can go all the way through the uterus either to the broad ligament, to the round ligament, or to the abdominal cavity during the course of the procedure.

So, in addition, as one attempts to get those uterine parts, extra passages with the instruments can lead to further risk. So, it's repetitive passages of the instruments to complete the procedure to retrieve parts that may be missing, and then finally those parts themselves that can move outside the uterus as part of the process.

[453:19-21] (Johnson)

A. Yes. I think there are a substantial number of practicing OB-GYNs who believe that the intact D&E procedure has benefits compared to the traditional dismemberment procedure.

[479:18-23] (Johnson)

THE WITNESS: What I mean by that is that the people who do our D&E procedures try to deliver the fetus as intact as possible with as few procedures as possible. So if, as they do the procedure, if they are able to deliver the fetus intact, that would be fine. The fewer number of passes to do a dismemberment D&E is always our goal.

[526:1-530:8] (Hammond)

Q. And you have testified that you perform abortions; how long have you been performing abortions?

A. I began providing pregnancy terminations in the first year of my residency. I have continued since that time, so approximately 15 years.

Q. And what types of abortions have you performed over the course of your career?

A. I have provided both medical abortions and also surgical abortions.

Q. Can you describe for me what you mean by medical and surgical abortions, please?

A. Well, medical abortion involves giving some kind of medication or drug to induce abortion. So, in the first trimester of pregnancy you are inducing something akin to a miscarriage.

In the second trimester of pregnancy you are, in essence, inducing labor to cause a patient to deliver.

For surgical abortions, typically in the first trimester this involves suction curettage where we vacuum the uterine lining.

In the second trimester pregnancy it involves a performance of the procedure dilation and evacuation, commonly abbreviated D&E.

Q. Doctor, do you currently perform each of these types of abortions?

[527] A. Yes, I do.

Q. And approximately how many abortions have you performed in your career?

A. I have performed at least approximately 3,000 abortions since beginning my residency and probably a thousand or more D&Es.

Q. How frequently do you currently perform abortions?

A. I am currently scheduled to perform abortions each Tuesday and also each Friday; they are referred to the family planning service.

We often have to add extra procedures in because of the nature of our practice, so we will occasionally add them in that have to be done sooner and other times of the week, or even the weekend.

Q. What type of abortions are you currently providing in your practice?

A. Really all types I have been trained to do, so both medical and surgical abortions in the first as well as the second trimester.

Q. So that would include the procedures you have described for us a few minutes ago, the suction curettage and the medical abortion in the first trimester, and the dilation and evacuation and labor induction procedure in the second trimester; is that correct?

A. That is correct.

[528] Q. Doctor, what gestational ages do you perform abortions?

A. We currently provide abortions from very early in gestation, really as early as the pregnancy is diagnosed. So, approximately five weeks until 24 weeks.

Q. Do you have formal training in providing abortion care?

A. Yes, I do.

Q. Can you describe that for us?

A. Well, I received training when I was a resident in obstetrics and gynecology.

When I was at the University of Rochester obtaining training abortion training was optional but was routinely provided to residents, and I chose to learn how to do this.

So, I was trained in my residency program to provide surgical abortion through approximately 20 weeks' gestation.

THE COURT: Ms. Chaiten, is this a convenient time to take our afternoon break? Or do you have a little bit more you would like to do on this?

MS. CHAITEN: Your Honor, if I might just ask one follow up question and then it would be a fine time to take a break.

THE COURT: Of course. Go ride ahead.

BY MS. CHAITEN:

Q. Have you received any additional training in abortion care?

A. Yes, I have. After I finished residency I continued to provide [529] abortion care, but when I moved to Northwestern University had really only been trained through approximately 20 weeks' gestation.

At that point my boss was Dr. Marilyn Frederikson, she needed something to be able to assist with these procedures because there is a lack of people out there who are actually trained to do them. And she—in essence I was an apprentice to her as I gradually advanced the gestational age at which I was comfortable to 22 weeks.

And then, after approximately 2001, gradually advanced my comfort level, had advanced my comfort level to 24 weeks.

MS. CHAITEN: Your Honor, this would be a fine time to take a break.

THE COURT: Fine. The Court will stand in recess.

(Recess)

THE COURT: Before we continue I thought I would just tell all of you that having experienced two days of listening to this testimony, I would tell you in advance that when the hearing or trial was concluded I still want summations but I'm going to require written submissions on findings of fact and conclusions of law, which I am going to—at the time, I won't set a date of course—but it will be at the moment 10

days after the conclusion of the hearing, all right? Ms. Chaiten, you may inquire.

MS. CHAITEN: Thank you, your Honor.

[530] BY MS. CHAITEN:

Dr. Hammond, you testified earlier that you performed procedures called D&E, is that correct?

A. That is correct.

Q. Approximately how many D&E procedures have you performed throughout your career?

A. At least a thousand.

[533:9-20] (Hammond)

Doctor, in the context of your practice, approximately how many times have you performed an intact approach to D&E?

A. That's really hard for me to say because, again, we are dealing with this continuum of procedures where you're really looking at how intact constitutes an intact D&E. And, to be honest, we don't really think much about how intact we are doing it at the time. It's not something that we record or that we note or keep track of.

Now, I can tell you that in those procedures that I do between 20 and 24 weeks' gestation I am probably, in about half of all of those cases, able to extract a part of the fetal torso intact to the level of the fetal navel or above.

[563:15-23] (Hammond)

Q. Do you have an opinion regarding the safety of intact D&E?

A. I think it is a very safe procedure.

Q. Do you have an opinion as to the comparative safety of intact D&E to other second trimester abortion termination procedures?

A. I think D&E's generally are very safe procedures. But I think the more intact you can do a D&E, the safer it is for the patient. So I think intact D&E's are really the safest type, the safest variation, the safest evolution of D&E's.

[565:7-566:2] (Hammond)

Q. Dr. Hammond, I believe you were talking about the reasons why it is your opinion that the intact approach to D&E is the safest way to perform a D&E. I think you mentioned the decrease in the number of passes of instruments into the uterus. Would you continue with your answer, please.

A. Like I was saying, there are many other reasons that I think that it is safer to use the intact procedures. Another reason is simply that there is less of a chance to lacerate or to make a cut in the cervix. If you are doing this relatively intact, you have fewer bony parts of the fetus that are exposed that can cut into the cervix as you remove them from the patient. So the more intact the fetus, the less chance there is for those to cut the cervix and injure the patient.

Another reason is simply the degree of surgical control that we have. With very intact procedures, when I have control over the fetus external to the cervix, I can see a large portion of the procedure that I am doing. I am not having to blindly grope inside the uterus like I am with a more disarticulated or dismembered D&E, and therefore have a [566] drastically lower likelihood of perforating the uterus and injuring the cervix, because it is all exposed.

[568:19-571:18] (Hammond)

Q. Why does intact D&E reduce the risk of uterine perforation?

A. Again, there are several reasons. First of all, I am just not reaching into the uterus as frequently. Secondly, when I am reaching in, I am not having to rely solely on feel. I have greater control of the fetus, often operating almost directly in front of me external to the cervix. So I am not reaching into the uterus as frequently, I don't have dismembered fetal [569] parts in the uterus that can poke through the uterus, and I have far better surgical control throughout the procedure.

Q. Doctor, you also testified that one of the advantages of an intact D&E is reducing the risk of cervical laceration or uterine perforation due to the fact that the presence of sharp

bony fetal parts is reduced. First of all, can you tell us, what is cervical laceration?

A. It is a cut or a tear in the cervix, a scrape in the cervix.

Q. What causes the presence of sharp bony parts in the first place?

A. Disarticulation or dismemberment of the fetus.

THE COURT: Have you ever lacerated a cervix?

THE WITNESS: I am sure at some point that I have, your Honor. I don't specifically recall a circumstance right now.

Q. Doctor, why is the presence of sharp bony fetal parts associated with laceration and perforation?

A. In terms of perforation, obviously if you have a sharp object that is inside of the uterus and you are reaching in somewhat blindly into the uterus to grasp that sharp object, you can either directly push that object through the uterine wall or indirectly do so as whatever other parts jostle that object inside the uterus.

In terms of cervical laceration, if you have exposed [570] bony fragments and you are extracting them through this ring-like structure, which is what the cervix is, they can scrape against the cervix as you remove them and lacerate the cervix.

Q. Why does intact D&E reduce this risk?

A. If you are doing the procedure intact, again, you don't expose those bony fragments, the fetus remains intact. It is more akin in many degrees of intactness to a standard delivery.

Q. Another advantage that you mentioned earlier was the reduction of retained fetal tissue or parts. What does that mean?

A. Retained parts just means that we leave something behind. It can be either the placenta or it can be part of the fetus. As I was indicating earlier, one of the things we do at the end of the procedure is to make a mental note as to whether we think that we have extracted everything that might have been inside.

In some of the cases that I have seen, that is not nearly as easy as it would seem. I have seen patients referred in because they have fetal anomalies. So I have cases where the baby doesn't have much of its head or may be lacking extremities or any of the other landmarks that we commonly use to tell us whether we have extracted everything that we need to extract.

So if I have done this intact and have an intact fetus in front of me, then I know that I have done at least an intact [571] extraction of the fetus and have nothing else that I need to look for.

Q. Why is it important to make sure that you have removed all the fetal tissue and parts from the uterus?

A. With respect to both the fetus and the placenta, if you leave tissue inside of the uterus, the patient is at an increased risk for coming back with either an infection or a hemorrhage. Most of the time the patient will simply pass the tissue and will be fine, but many patients don't, and we eventually have to evacuate that material under less than optimal circumstances.

Q. Why does intact D&E reduce the risk of retained fetal tissue or parts?

A. As I had just indicated, because we have seen the fetus delivered. We now at that point that there is nothing that we have dismembered or disarticulated that could be remaining behind inside of the uterus. It is all at that point present and accounted for.

APRIL 1, 2004

[588:19-590:7] (Hammond)

Q. Doctor, you also mentioned that patients with chorioamnionitis would be offered particular advantages by undergoing an intact approach to D&E, is that correct?

A. Yes, that's correct.

Q. Just remind us briefly [589] what chorioamnionitis is. I know we have defined it before, but there are a lot of medi-

cal terms here. Just for the benefit of the rest of us, can you briefly remind us what that is.

A. It is an infection of the fetal membranes and also the amniotic fluid. We commonly, in case I lapse into this, will abbreviate it "chorio" for short.

Q. Why is it that a patient with chorioamnionitis would benefit from an intact approach to D&E?

A. There are a couple of reasons. First of all, these are patients who are already at higher risk of uterine perforation. If the uterus is infected, the wall doesn't have the usual turgor, the rigidity that it would have if it were not infected. Because of that, because of doing the procedure, as I testified, more intact decreases the likelihood of perforation, it is even more important in this kind of patient who is at higher risk.

There is another even more compelling reason, though. The more you manipulate the inside of the uterus when it is an infected environment, the more likely you are to seed the infection from the uterine lining into the blood and take a localized infection like chorio and make the patient septic, which I testified yesterday is a more disseminated infection and vastly more dangerous to the patient.

So when I am doing a D&E on somebody who has chorio, I am going to try to do the procedure with the minimum number of passes, the least intrauterine instrumentation that I can, so that I don't make the patient sicker in the process of doing [590] this.

Q. Does a patient who has chorioamnionitis have to terminate the pregnancy?

A. The pregnancy must be delivered, yes.

Q. Why is that?

A. Because it is the only way that you are really going to eventually treat the infection. You must evacuate the uterus.

[592:2-9] (Hammond)

Q. What are the benefits of that control of an intact procedure?

A. The benefits of the control are that I am not reaching into the uterus and having to somewhat blindly go after disarticulated or dismembered parts. I can see and feel everything that I am doing, because it is closer to me. So I am never at as heightened a risk of perforating the uterus or lacerating the cervix.

[594:10-17] (Hammond)

Also, one of the more common clotting factor problems, you had asked about these, is something called von Willebran's disease. It is a problem with, I won't belabor this, but the factor 8 complex, which is also involved in hemophilia. It is much more common, it is much more common in women. We do see this. And there is a drug called DDAVP, which they can actually give nasally immediately beforehand when we know exactly when the patient is going to deliver.

[597:10-15] (Hammond)

Q. Doctor, do you do anything different when dilating for an intact D&E than when you dilate for any other D&E?

A. Again, as I testified, I consider all D&E's part and parcel of the same procedure. The truth is we do nothing differently before our intact procedures, our relatively intact procedures, than for those that are done by dismemberment.

[639:2-644:17] (Hammond)

You testified earlier that the word "intact" does not appear in the Act's definition of partial-birth abortion, is that correct?

A. That is correct.

Q. Is that a concern for you?

A. Yes, it is.

Q. And why is that?

A. Well, as I think I mentioned earlier, I believe that many of even the dismemberment D&Es that I performed eventually fall within the scope of the ban.

Q. The statute says, partially vaginally deliver a living fetus; does that help you to understand better whether dismemberment procedures would be covered by the ban?

A. Well no, it doesn't, because it's possible, as I was testifying, to have started this delivery, have dismembered part of the fetus, and yet the fetus could still have a sign of life such as a heartbeat, and I could then deliver the remaining part of the fetus above the level of the navel and I believe sweep into, and I believe in those circumstances could potentially have violated the ban.

Q. In that situation, would you have partially delivered a living fetus—I'm sorry—partially vaginally delivered a living fetus?

A. Yes, I would.

[640] Q. And would you have delivered it to a level past the umbilicus, or the navel?

A. Yes.

Q. And, in doing so, would you then take steps that you know would kill the fetus?

A. Many of the steps that we take during the abortion know that the fetus will not survive.

Q. And would—

THE COURT: The moment you dismember it it is going to bleed to death, isn't it?

THE WITNESS: But we don't know exactly when demise is going to occur, your Honor.

THE COURT: But start it.

THE WITNESS: Yes.

BY MS. CHAITEN:

Q. In taking those steps, in partially delivering the living fetus to a point past the umbilicus, would your purpose be to enable yourself to take steps that you know will kill the fetus?

A. Well, my purpose is to evacuate the uterus and complete the procedure. It's not specifically to do those portions of the procedure you described.

Q. Doctor, you mentioned that you were concerned that some of the induction termination procedures that you perform could come within the scope of this ban, is that correct?

[641] A. That is correct.

Q. Can you explain how that could happen?

A. Well, I can certainly describe some scenarios which could potentially trip the ban.

Let's say that you had initiated an induction procedure. Keep in mind that an induction procedure is not a, quote unquote, natural event, it is a deliberate and intentional act with the prospect, eventually, of a vaginal delivery.

But let's say that the fetus starts to deliver but delivers such that the calvarium, the head, is entrapped behind the cervix. That isn't a preposterous kind of assumption or scenario because if you were inducing, let's say an infant with hydrocephalous or any kind of enlargement or disproportion of the head and the rest of the body, the head is the largest part and could get stuck at the cervix.

Now, what do you do under those circumstances? Well, this kind of scenario could result in an obstetrician who really has had—has tried in good faith not to violate what they might perceive this ban to be to now have to try to assist the patient in completing this process.

And what we usually would do is analogous to a D&E. It's one of the reasons why the National Abortion Federation clinical policy guidelines are if you do a medical induction abortion you are supposed to have the instruments for D&E on [642] hand also in case you get stuck and have to finish the procedure surgically.

But let's say that the person doing the procedure didn't know how to, with the entrapped calvarium, with the entrapped head to reach up, perform a decompression procedure and complete the process as I have already described. Well, they might, in the process of trying to even just do a

delivery, do an act which could be interpreted as the overt act.

Let's say they try to deliver a 20 week gestation where the neck is simply not as stable as what you might think with a full-term baby. We've had cases where people have – we being at Northwestern where people have attempted to do these deliveries and have evulsed, they have basically torn a great deal of the neck if not tearing it off just trying to deliver the rest of the baby.

And so, in that case that person could have violated the Act because they know the fetus isn't going to survive that act.

Q. Doctor, in that example what would have to be done in order to then deliver the fetal head?

A. Well, you would have to do it instrumentally, just like we do for a D&E.

You need to reach in with one of the forceps that we use and do an act that would collapse the calvarium.

[643] Now, again, because we have been talking about collapsing the head in many ways that doesn't always involve putting scissors in and, certainly, if it has been disarticulated we wouldn't do that. We would reach in with our forceps and take the head out.

Q. And in order to do that you would have to collapse the head?

A. Oh, you always have to collapse the head with the D&E procedures to get the head out.

Q. In every D&E?

A. That's correct.

Q. Doctor, in performing an intact D&E, do you deliver the fetus to a certain point for the purpose of performing an act that you know will kill the fetus?

A. No, I—in any D&E, including intacts, I deliver the fetus as intact as possible to get the operation over with.

Q. Doctor, in the induction example that you gave us where the head got stuck and you needed to proceed in the same

way that you might with an intact D&E, are the steps that you take deliberate and intentional?

A. Yes, they are.

Q And, in that scenario, do you deliberately and intentionally vaginally deliver the fetus?

A. Yes, I do.

Q. And what is the deliberate and intentional act that begins [644] the delivery of the fetus into the vagina in an induction?

A. Giving the medicine that starts the delivery process.

Q. Do you deliberately and intentionally deliver the fetus to a point past the navel?

A. In many cases, yes, because the uterus itself is going to start that process and effect that delivery. And if it's incomplete we are going to have to help the delivery process continue.

Q. And what would the overt act be, in that scenario?

A. It could be, in the scenario where you described where the fetus becomes stuck, it could be any act that can result in the demise as I extricate the baby, anything from disarticulating at the neck to collapsing the calvarium and so forth.

Q. Do you deliberately and intentionally perform the overt act in this situation?

A. Every act that I do in most abortions is deliberate and intentional.

[665:22-666:3] (Hammond)

Q. What's the dose of propofol given to a patient who is undergoing intact D&E, Doctor?

A. I would—I think they give the same dose to all of our—the same appropriate dose to our patients and don't change the [666] dose based on whether we are performing the D&E any differently. Because, like I said, a D&E is pretty much a D&E to me.

[742:5-751:4] (Westhoff)

Q. And do you, yourself, perform abortions, Dr. Westhoff?

A. Yes, I do.

Q. For about how long have you been doing so?

A. I started performing abortions during my residency training at Kings County Hospital and there have been, over all these years, changes in the scope of practice. So I started providing abortion in the late 1970s and continued to do so today but there have been a few, several years in between where I was not providing abortion care because my energies were focused elsewhere.

Q. But for most of the time since 1978 can you give the Court an approximation of how many abortion procedures you've performed?

A. I'm sure it's more than several thousand and I would need to think year by year what I was doing to try to add up, but.

Q. I think we probably don't need—

A. Okay.

Q. I don't think we need that unless the Court would like to inquire. Do you currently perform abortion procedures?

A. Yes, I currently do provide abortion procedures.

[743] Q. Is that at the specialty services, at Allen Pavilion?

A. Yes, at special GYN services and in private practice.

Q. Approximately how many abortion procedures are performed at the special GYN services unit each year?

A. The unit, overall, provides abortion care for about 2,000 patients per year.

Q. And you don't do all of those?

A. I do not do all of those.

Q. What type of abortion procedures are performed at special GYN services?

A. We provide, in the first trimester, both surgical abortion, vacuum aspiration abortions, and also medical abortion using mifepristone and misoprostol. And in the second trimester we provide surgical abortion, D&E.

Q. And in the past, Dr. Westhoff, what other abortion procedures, if any, have you performed?

A. In past years I also performed second trimester induction abortion and particularly used the saline installation method, although I have in the past done other kinds of induction abortions as well. But that's not currently part of my practice.

Q. Have you, in the past, Dr. Westhoff, performed hysterotomies?

A. I have, on a few occasions, performed hysterotomy for abortion.

[744] Q. How many induction procedures have you performed over your career, Dr. Westhoff?

A. It certainly has been several hundred. I don't know the exact number.

Q. Are you familiar with the use of prostaglandins to induce preterm uterine contractions?

A. Yes, I am.

Q. Have you authored any publications or instructional materials concerning that use?

A. Yes. On behalf of the American College of OB/GYN I helped prepare a teaching tape for doctors to learn about the method of emptying the uterus with using prostaglandins.

Q. Do you remain current, Dr. Westhoff, on literature in the field regarding induction procedure?

A. I try to remain familiar with the literature.

Q. At about what gestational age, Dr. Westhoff; does your service perform suction curettage procedures?

A. We perform suction curettage starting from the, whatever early gestational age a woman might present seeking such a treatment. We don't have a lower limit as long as we can make a diagnosis of pregnancy, and we continue using the suction curettage technique through the first three months of pregnancy. So, certainly up to 12 or 13 weeks. [745] And there are some patients where suction curettage is successful even early in the second trimester.

Q. At about what gestational age does the special GYN service perform medical abortions?

A. We perform medical abortions just through nine weeks, until nine weeks after the last menstrual period.

Q. You made reference in an earlier answer, I think to the use of mifepristone in the medical abortions that you do?

A. Yes.

Q. Does that go by another name?

A. Mifepristone is formerly known as RU-486.

Q. At what gestational age does your service perform D&E, Doctor?

A. We perform D&E throughout the second trimester, from the beginning of the second trimester about 14 weeks' gestation through 23 weeks and six days' gestation.

Q. Does the service perform the variation of D&E known as intact D&E?

A. Yes, we do.

Q. At about what gestational age do you begin to do that?

A. In general we use that approach in the later part of the second trimester, perhaps starting around 18 or 19 weeks, but there are—it's not an exact threshold. Each case is different.

Q. How many D&E procedures, approximately, of any variation, [746] does your service perform each year?

A. In 2003 our service performed about 250 D&Es.

Q. You said 250?

A. I think so.

Q. And approximately how many of those involve or involved, in 2003, if you know, intact D&E?

A. We haven't had the practice of keeping any kind of census where we distinguish what kind of D&E we did, so I don't have any sort of statistics to support that number. But my general recollection is that it would be at least 50 of the D&Es last year would have been intact D&Es.

THE COURT: Is there any time when you did keep such a record at your institution as to what type of D&E was done at the institution?

THE WITNESS: No, your Honor. We have not kept records with that kind of breakdown.

Q. Can you explain for the Court the basis for your judgment not to keep those sorts of breakdowns?

A. Well, all of these cases are variation on D&E. The main fact for us is that we did perform a D&E and I think a lot of documentation sometimes is driven by requirements to match the coding that exists, the procedure coding, diagnosis coding and so on, and there exists no special coding for different variations on D&E. They're all coded the same.

Q. In addition to the procedures, the D&E procedures that you [747] personally performed, what is the basis for your general recollection that the order of number of D&Es that you do each year is about 50, or that did you in 2003, perhaps?

A. One reason I have for giving that number is just the way our week is structured. We perform our D&Es on Fridays, which means we do cervical preparation with laminaria on Wednesdays and Thursdays. I have assigned myself to see patients on Wednesday on this service so that that means I'm likely to see most of these patients when they have, when they begin their cervical preparation, they begin getting ready for the D&E. And so, that just gives me a sense of who the patients are going to be and it gives me a sense that probably every week we have at least one such patient. In addition, I just discuss with all of my colleagues who share the coverage of the operating room on Friday what their impression is about doing these cases.

Q. Of the types of abortion procedures performed at the personal GYN service, which do you currently perform, Doctor?

A. I perform all of the—some—I take care of some cases for all of the types of treatments that we offer, although I don't currently perform tubal ligations.

Q. And with respect to those treatments, can you give the Court an idea of how many are involved, say, with respect to suction curettage, for example?

[748] A. Sure. In the year 2003 I probably performed, personally, about 500 suction curettage, some give or take a hundred. And I probably personally performed or personally supervised, in the operating, room about 50 D&E cases.

THE COURT: You supervised or you performed?

THE WITNESS: Well, since we're a teaching institution we often will have more than one doctor in the operating room at the same time, and so sometimes I'm right there working with another doctor but I might not be the main person who actually has my hands on the patient.

THE COURT: How many times do you have your hands on the patient in that setting in that procedure?

THE WITNESS: I haven't thought about distinguishing that previously so I just need to think about my answer and—

THE COURT: Well, I would think you know what you did last year. I mean, roughly. I'm not asking you for an exact count.

THE WITNESS: No. Because an important part of my role in taking care of patients is also to teach other doctors. I want the doctors working with me to provide as much of the direct hands-on care as they are competent to do. And often my role there is to help or guide them rather than to carry out the case alone and so I would—

THE COURT: Would it be fair to say then that you [749] supervised them all but you do the hands-on?

THE WITNESS: In the majority—yes. And I mean I will be there with my gloves on so-to-speak, but in the majority of cases it will be the other doctors I'm working with who are actually doing more than I am.

[750] THE COURT: You are primarily the supervisor then, is that correct, fair to say?

THE WITNESS: Yes, that is fair, your Honor.

BY MR. HUT:

Q. Approximately how many D&E procedures, Dr. Westhoff, have you performed throughout your career?

THE COURT: Could we have this clarified that we are talking about supervising or actually performing them hands-on, if you could break that out.

Q. If you could distinguish that for the Court and answer my question, please do so.

A. Until we started this service three years ago at the Allen Pavilion, I was performing only a small number of D&E's. We didn't have a service at our hospital. Since we started the service, it is more cases, and I would say in the—again, looking back just at 2003, I was probably in the operating room helping take care of about 50 patients having D&E's. But, as I said a moment ago, that is a mixture of hands-on and supervisory care, which is the nature of a teaching service.

Q. If you extend that back beyond 2003, going back to the time you first began to perform D&E, can you give us an approximation of the number of times you performed D&E?

A. Our service was a little less busy in 2001 and 2002, so I think the numbers were a little less in those years. And prior to 2001 the numbers would have been much smaller, because [751] we didn't actually have a whole service of our own.

Q. Does the number of D&E that you indicated you performed or supervised in 2003 include the intact variation?

A. Yes, it does.

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[779:7-8] (Westhoff)

A. The CDC reports that in the United States about 95 percent of all second trimester abortions are performed using D&E.

[786:22-787:18] (Westhoff)

But once the cervix is stabilized we will then insert finger or uterus—finger or instrument into the uterine cavity to begin to pull down fetal parts. In general, in our cases, we have a sonography unit in [787] the room with us standing by but we decide on a case-by-case basis how much we want to use sonography during the case.

THE COURT: That's a sonogram?

THE WITNESS: Sonogram, ultrasound, yes; to take, to image the fetal portion, the fetal parts and position.

Q. Does that conclude the description, Doctor?

A. At this point we will begin the extraction of the fetus or the evacuation of the fetus, and we can do this with a combination of traction with instruments or digital traction, until we remove the entire fetus from the uterus. When we have removed the entire fetus, if it is in parts we do enumerate the parts to feel confident that all the fetus has been removed. And then we will remove placenta and membranes using a combination of suction curettage and sharp curettage.

Q. You mention traction in your answer, Dr. Westhoff; what is traction?

A. Traction just means pulling.

[791:17-792:6] (Westhoff)

Q. In your D&E practice, Dr. Westhoff, how much of a fetus may be removed by the physician with the [792] first pass of instruments during a D&E?

THE COURT: Meaning herself.

Q. Herself or her service; to the extent she is familiar with it.

A. Myself, that's fine. In my own experience, my own personal experience there is a very wide range of possibility where sometimes with the first pass of instruments in fact we do not succeed in removing any fetal parts so we can have an unsuccessful pass. And we can introduce instruments and remove the entire fetus at the first pass of the instruments. And of course every possibility in between

those two extremes, which have all in fact occurred in my very own practice.

[793:2-794:5] (Westhoff)

Q. Have doctors performing D&E in your service, under your supervision, had uterine perforations during the course of D&Es they have performed, Doctor?

A. Yes. As I was saying yesterday, I'm responsible for assessing all of our complications in order to make sure that we're taking good care of our patients and see what's going on. In the last three years on our service we have had one cervical laceration and we have had three perforations of the uterus during D&E procedures.

THE COURT: Were these done by interns or residents?

THE WITNESS: They were done by other attending physicians or—

THE COURT: I didn't ask you that, Doctor. My questions are very simple.

THE WITNESS: No.

THE COURT: They were not done by residents.

THE WITNESS: They were not done by interns or residents.

THE COURT: Either one.

THE WITNESS: I know who was involved in each of these cases and it was not interns and residents.

BY MR. HUT:

These perforations and lacerations occur in D&Es that were [794] effected with dismemberment or more relative intact, Doctor?

A. Each of these cases I am referring to occurred during a dismemberment type of D&E. We have had no lacerations or perforations on my service with the use of an intact variant of D&E.

[794:11-16] (Westhoff)

My preference is to minimize the passes of instruments into the uterine cavity and my corollary preference is to re-

move as much of the fetus in each pass as possible and the, sort of logical goal of that is if I can remove the fetus intact I will do so. But we have to see each step of the way as we proceed, if that's possible.

[797:25-798:14] (Westhoff)

Q. During the midtrimester, Dr. Westhoff, what is usually the [798] largest part of the fetus?

A. The largest part is the skull itself and, in particular, we pay attention to the diameter across the skull.

Q. When any part of the fetus is too large to pass through the cervix during the course of a surgical abortion in the midtrimester, how do you remove the part in question?

A. For any fetal part that's too large to fit through the cervix we attempt to remove—reduce the diameter of the fetal part by severing, crushing it, or collapsing it.

Q. How often will it be necessary to collapse the fetal skull during D&E whether the D&E proceeds by a dismemberment or more relatively intact, Doctor?

A. For the vast majority of D&Es it will be necessary to either crush or collapse the fetal skull.

[802:9-14] (Westhoff)

Q. Based on your review of and familiarity with CDC statistics, Dr. Westhoff, what percentage of second trimester abortions are performed using the procedures you have just identified?

A. The best estimate is about 95 percent are D&E and about 5 percent are induction.

[805:2-7] (Westhoff)

Q. Without delving into the relative safety of different methods of abortion, do you have an opinion on the impact of increased gestational age of the relative safety of abortion?

A. Yes, sir. Abortion is safest in the early weeks of pregnancy, and as the gestational age advances, the risks and complications increase as well.

[810:16-811:11] (Westhoff)

A. Both approaches are very safe. In the earlier part of the second trimester, up to 16 weeks or so, the uterus is less sensitive to the induction drugs, and so I think D&E is substantially safer because it is more likely to be successful in the earlier part of the second trimester.

In the later part of the second trimester, in general, D&E and induction are similar. However, that depends on the resources available when taking care of the patient, because they are not going to be equal in all hands.

Q. With respect to the later part of the second trimester, do [811] you have an opinion why D&E is the more common in that portion if, as you have testified, the procedures are, subject to your testimony, approximately comparable in safety?

A. Yes. An induction abortion involves hospitalization for a period of several days, during which a woman goes through essentially the experience of labor. This is painful and difficult for all women. In particular, my patients find that would be very distressing when they are ending a wanted pregnancy, and they would prefer to have a D&E with less time in the hospital and the opportunity to undergo the abortion itself in a very short period of time while they are asleep.

[824:12-825:7] (Westhoff)

Q. Do you have an opinion, Dr. Westhoff, regarding the safety of the intact variation of D&E?

A. Yes, I do.

Q. What is your opinion, Doctor?

A. My opinion is that the intact variation is safer for the woman than the dismemberment variation of D&E.

Q. Why in your opinion is the intact variation safer than the dismemberment variation for the woman?

A. Because we minimize the number of passes of instruments into the uterus, we can reduce or possibly eliminate the risk of perforation of the uterus or laceration of the cervix that is directly due to the instrument itself. Also, be-

cause in dismemberment D&E the fetus is removed in parts, there are bony fragments, and it is possible for the bony fragments to cause [825] perforation or laceration. With the intact variation, that risk is decreased or eliminated. Also, with the dismemberment D&E there is a risk of small portions of the fetus remaining behind in the uterus, and that can lead to hemorrhage or infection of the uterus subsequent to the procedure. When the fetus is removed intact, that risk is reduced or eliminated.

[838:18-25] (Westhoff)

Q. —do you recall the names of any of the other investigators associated with Dr. Chasen in the study?

A. Yes. I don't know all of them. Do you want me to tell you the names of the ones I know?

Q. Yes, and their affiliations, to the extent you know those as well, please.

A. Sure. Dr. Frank Chervenak, who is chairman of obstetrics and gynecology at the Cornell campus of the New York Presbyterian Hospital is one of the authors; Dr. Bill Rashbaum who is an attending physician there; Dr. Jane Kaufman who did her training the Cornell campus of New York Presbyterian and who now is attending physician on my service at Presbyterian. And I think there are one or two additional authors but I don't know those individuals.

[840:4-12] (Westhoff)

Q. Dr. Westhoff how, if at all, does the study performed by Dr. Chasen and its conclusions, affect your view of the intact variation of D&E as compared to dismemberment variation?

A. The results of Dr. Chasen's study confirm my impression that intact D&E is a safe alternative for my patients and is less likely to result in serious complications than a dismemberment D&E. So, his results from his patients conforms to my clinical experience.

[841:20-22] (Westhoff)

A. Among the range of alternatives I usually think, for most of my patients, that intact D&E offers safety advantages compared to those alternatives.

[854:3-862:20] (Westhoff)

As in the case we were discussing previously where the fetus was entirely intact, subsequent steps would include cutting the umbilical cord and collapsing the skull, either one of which would be more rapidly lethal.

Q. And why is it that you would perform such acts?

A. In order to continue the procedure and to empty the uterus safely.

Q. And at the time that you would collapse the skull or cut the cord, is the fetus still living?

A. Yes. It would be likely to still be living.

Q. And as with the last example, is the cutting of the cords or the collapsing of the skull an act that you know is lethal?

A. Yes.

Q. Are the steps that you have just described in performing the variation of dismemberment D&E discussed, performed by you deliberately and intentionally?

A. Yes.

Q. What is your purpose in performing a D&E involving dismemberment such as the one you have just described?

A. It is to, as safely as possible, complete the abortion.

Q. Doctor, would you fear prosecution under the Act for D&E by dismemberment and the way you just described it?

A. Yes, I would.

[855] Q. Do you have any other examples or scenarios of the way D&E with dismemberment might proceed given its variability that would involve vaginal delivery of a living fetus until a point at which any part of the fetal trunk, past the navel, is outside the body of the woman?

A. Yes. Certainly, I can. An example that I have in fact experienced myself in taking care of the patient in the recent past involved not being able to start the procedure by bring-

ing the feet down, using forceps and in fact first delivering part of the fetal back entirely separate from the patient. So, that is a part of the fetal trunk above the navel that was delivered outside of the woman's body as a separate piece of the fetus. We were then able to continue bringing the fetus down and bring the legs down and ultimately completed the abortion. I don't remember in that case all the exact subsequent steps, but we did bring out a piece of the trunk first while the fetus was still living. So, I fear that that particular sequence of events would also violate the ban.

Q. And in the sequence that you described, did you perform an overt act after the evacuation of the portion of the fetal trunk above the navel and while that portion was outside the body of the woman?

[856] A. Yes. And in that case, as it evolved, we also cut the cord and collapsed the skull, both of which are lethal acts.

Q. Again, why did you perform those lethal acts in the situation you just described?

A. In order to continue emptying the uterus and in order to continue the abortion.

Q. And at the time you performed the first of the cutting of the cord or the collapsing of the skull, was the fetus still living?

A. Yes.

Q. And at the time you performed either the first of the cutting of the cord or collapsing of the skull, did you know that such act, as performed, would be lethal?

A. Yes.

Q. Did you perform the acts, in the abortion you just described, deliberately and intentionally?

A. Yes.

Q. Now, in a dismemberment D&E, do you deliver the fetus to a certain point for the purpose of performing an act that you know would kill a fetus?

A. I go step by step for the purpose of completing the entire abortion and I know that in the course of proceeding step by step I will perform a lethal act, but—

Q. Is that step-by-step process the same for an intact D&E, [857] Dr. Westhoff?

A. Yes, it is.

Q. Now, Doctor, I would like to turn your attention or have you turn your attention to the applicability of the Act to the induction. Does vaginal delivery—

MS. GOWAN: Object to the form of the question.

THE COURT: What's your objection?

MR. HUT: I will rephrase it, your Honor.

Q. Does vaginal delivery occur, Dr. Westhoff, in an induction?

A. Yes; vaginal delivery occurs during an induction abortion.

Q. When you perform an induction abortion, is the fetus living when you commence the vaginal delivery?

A. Yes, it is.

Q. Based on your experience in performing an induction, has it ever occurred that you have vaginally delivered a living fetus until a point at which any part of the fetal trunk, past the navel, is outside the body of the mother?

A. Yes.

Q. Now, directing your attention to the phrase, "an overt act that the person knows will kill the partially-delivered living fetus," does it ever occur, in the course of an induction procedure, that a physician must perform an overt act that he or she knows will kill the fetus?

A. Yes.

[858] In an induction in the midtrimester it is very likely that the fetus will present in the breech position to start out with, as I said earlier.

And so, as the induction proceeds, the fetus may in fact deliver feet-first. And typically the cervix will not yet be

sufficiently dilated for the larger parts of the fetal body to pass readily through. It is common for there to be some tension on the cord which may be wrapped around the body.

So, a very common occurrence during an induction delivery of a breech would be to cut the cord along the way. And in the case of a midtrimester abortion, that would be a lethal act.

Q. And when you would cut the cord in the situation you just described, would there be a part of the fetal body past the navel—excuse me, part of the fetal trunk, past the navel, outside the body of the woman at the time that you performed the lethal act?

A. Yes, it would be.

Q. And at the time you performed the lethal act, would the fetus still be living?

A. Yes, it would be.

Q. And would the cutting of the cord, as you just described it, be an act that a physician knows will kill the fetus?

A. Yes.

Q. In the type of induction that you just described, [859] Dr. Westhoff, are steps taken deliberately and intentionally?

A. The overall plan of the induction is deliberate and intentional and if the fetus delivers to that position, any subsequent action by the physician is deliberate and intentional; yes.

Q. Dr. Westhoff, will you explain why it is that physicians have a role in treating spontaneous abortions?

A. Spontaneous abortion or miscarriage can occur throughout gestation, and many spontaneous abortions do not complete on their own, the patient requires physician assistance to complete the emptying of the uterus.

And there is some portion of cases where women might complete the delivery entirely without intervention, but I would say in the majority of miscarriages, of which there are about 800,000 per year in the United States, in at least 75 percent some medical intervention is required.

In particular, in the second trimester the cervix may be open and the patient may be bleeding or may have infection, and this can only stop or be remedied through the completion of emptying the uterus. And so, a physician must take some action to help the miscarriage be completed.

Q. And is the action the physician may take in emptying the uterus something that involves vaginal delivery?

A. Yes, it does.

Q. And when a physician may treat spontaneous abortion, may [860] the fetus be still living when you commence with the vaginal delivery?

A. Yes, it may.

Q. Based on your experience, Dr. Westhoff, in managing spontaneous abortion, has it ever occurred that you have vaginally delivered a living fetus at the point at which any part of the fetal trunk, past the navel, is outside the body of the mother?

A. Yes, I have.

Q. Directing your attention to the phrase "overt act the person knows will kill the partially-delivered living fetus," does it ever occur, in the course of treating a spontaneous abortion, that the physician must perform an overt act that she knows would kill the fetus?

A. Yes, it does.

Q. Can you provide us with an example?

A. Well, there are two patients very recently taken care of, both of whom were miscarrying wanted pregnancies.

In one case the cervix started to dilate and the patient was around 20 to 22 weeks. I don't remember the gestational age exactly, but the cervix started to open and the amniotic membranes became infected, so she had a condition called chorioamnionitis, and that is dangerous to the woman she can become septic. Her entire body can become infected if all the infected tissue is not removed from the uterus.

[861] Because her cervix started to dilate she didn't need any laminaria treatment, for instance, but we took her to the OR for a D&E in order to complete the miscarriage.

In another recent patient, the membranes ruptured prematurely and the fetus, while still alive, was not growing further. And after three weeks it became clear that ultimately the prognosis for the fetus was fatal, it was not going to be able to grow and survive this.

So, we dilated the patient's cervix with laminaria and went to the OR to perform a D&E. So, these were both miscarriages that did not complete on their own and we needed to take care of the patient to complete the miscarriage.

Q. In these or any other cases that you have seen, does it occur that there is a part of a navel—excuse me—a part of the fetal trunk past the navel that is outside the body of a woman at a time that the physician must perform an overt act that is lethal?

A. Yes.

THE COURT: Keep your voice up, Mr. Hut, please?

MR. HUT: Sure, your Honor.

Q. And in those situations or any other, what type of overt act might a physician have to perform?

A. Certainly it may be cutting the umbilical cord, and also in these cases the collapse of the skull.

Q. And at the time of the collapse of the skull was the fetus, [862] in these cases, still living?

A. Yes, it was.

Q. And why did you perform the collapsing of the skull in these cases, or why do you perform collapsing of the skull and the cutting of the cord and any other treatment in the case of spontaneous abortion, Doctor?

A. In order to continue the procedure and accomplish the goal of emptying the uterus I need to proceed step by step and cannot complete it without carrying out those maneuvers.

Q. Is the collapsing of the skull or the cutting of the cord in such cases an act that the physician knows will kill the fetus?

A. Yes, it is.

Q. Are the steps taken by physicians in managing spontaneous abortion deliberate and intentional?

A. Yes, they are.

Q. What is the physician's purpose in managing a spontaneous abortion in the ways you have just described?

A. Overall, the main purpose is to maximize the health and safety of the woman and it is necessary to empty the uterus to

[884:17-885:21] (Westhoff)

Q. Doctor, with respect to testimony from you in the morning, why is it that the Chasen study confirms your view respecting the safety of intact D&E?

A. There are two reasons Dr. Chasen's results confirm my view. One is that among the complications that he reports on in his study, about 5 percent of patients in the intact group and 5 percent of the patients in the dismemberment group experienced complications. But in fact, on reading the details, all of the serious complications he reported, the most serious [885] complications were in the dismemberment group, and those actually are entirely analogous to the complications that we have observed in our own patient practice at Presbyterian.

Second, his overall conclusion is that the complication rates are the same in the two groups. But in his study the patients who underwent an intact D&E had a gestational age that was about two weeks greater than the gestational age of patients undergoing dismemberment D&E. Since we do know based on other existing data that the risk of complications increases with advancing gestational age, I would expect to see more complications in the subgroup that had a more advanced gestational age. The fact that they had the same overall rate of complications is, I think, something that favors intact D&E as being a safer technique.

I think that supports—

THE COURT: Does that mean you disagree with Dr. Chasen's report?

THE WITNESS: I think Dr. Chasen—

THE COURT: Do you disagree, ma'am?

THE WITNESS: I agree with his results. I think his conclusions are too conservative.

APRIL 5, 2004

[1017:11-21] (Westhoff)

A. "Some women require abortions because their pregnancies compromise their health. In some instances the patient has a pre-existing medical condition that is exacerbated by her pregnancy. For instance, women with certain kinds of heart disease are at increased risk during pregnancy with the risk of maternal and fetal death as high as 50 percent. Women who develop peripartum cardiomyopathy, a condition in which the heart muscle does not pump blood sufficiently are at sufficient risk of cardiac failure. Women with conditions such as kidney and liver disease may experience exacerbation of those diseases as a result of the pregnancy."

[1043:5-1046:2] (Frederiksen)

Q. You mentioned that you do D&E's and the intact variation, and earlier you mentioned that you provided abortion service. Can you describe to me the scope of your abortion practice.

A. I provide abortion services from approximately 4 or 5 weeks of gestation through 23 5/7 weeks of gestation.

THE COURT: 23 what?

THE WITNESS: And five-sevenths.

Q. What procedures do you perform?

A. I do first trimester dilatation and evacuation, or suction curettage. I provide second trimester terminations by laminaria and dilatation evacuation as well as the intact variation. I also do induction medical abortions in the second tri-

mester, and I provide medical abortion medications for the induction of early first trimester terminations.

Q. Approximately how many abortions have you performed in your career?

A. Thousands.

Q. Currently, how many do you perform per year?

A. Approximately 100 to 125 per year.

Q. Do you have specific training in abortion practice?

A. Yes, I do.

[1044] Q. Can you describe that, please.

A. During my residency, there was an abortion service at the Boston Hospital for Women, and all residents rotated through that. We received training in dilatation and evacuation as well as abortion induction in the second trimester.

Q. Have you had any additional abortion training since your residency?

A. Formal training, not per se. It is a matter of evolution of the existing procedures and extension of their services beyond what it was during my residency.

Q. How does that evolution occur?

A. It is a process by which we communicate with other physicians or have availability of better equipment or better pharmacological means to attempt different techniques as we provide abortion services.

Q. You mentioned that you perform a procedure known as dilation and evacuation, or D&E, is that correct?

A. Yes.

Q. Approximately how many D&E procedures have you performed throughout your career?

A. I really don't know, but probably thousands.

THE COURT: Thousands, plural?

THE WITNESS: Thousands, plural.

Q. You also mentioned a variation of D&E known as intact dilation and evacuation or intact D&E, is that correct?

[1045] A. Yes.

Q. Briefly explain what that term means as you understand it.

A. It is a procedure by which you use serial laminaria in the cervix over a period of time, after which there is adequate dilatation to allow extraction of the fetus relatively intact.

Q. Can you also assure that the fetus will be removed intact?

A. No, I can't.

Q. Why is that?

A. During the process of doing those techniques, you may encounter resistance to the cervix. The fetal tissues are relatively fragile, and you can't guarantee getting the fetus out totally intact.

Q. Do you ever perform a D&E using the intact approach?

A. Yes.

Q. Do you do those as part of your regular practice?

A. Since my training in the seventies, I have gradually changed the protocol under which I operate and have found that when I can get the fetus out relatively intact, I can ensure that there is no retained fetal tissue within the uterus, decreasing the risk of infection. The procedures are generally shorter, and the blood loss and the anesthesia time is less for the woman, so that it is a safer procedure.

Q. Approximately how many times have you performed an intact D&E?

A. I don't know.

[1046] Q. Why can't you tell us?

A. I have no mechanism. I don't keep track of it.

[1053:7-20] (Frederiksen)

Q. Dr. Frederiksen, does your opinion regarding the safety of second trimester D&E procedures include an approach that would be the intact approach to D&E?

A. Yes.

Q. Do you have an opinion as to whether intact D&E is ever safer than other abortion procedures?

A. An intact D&E is always safer because the fetus comes out relatively intact, involving less passes of the instruments into the uterus. It also has no ability to leave fetal parts within the uterus. There are less bony parts or bony fragments which can lacerate or cut the cervix as they are delivered from the uterus. And there is less blood loss overall.

Because the procedure is with the intact delivery of the fetus, the placenta usually delivers intact as well.

[1056:14-24] (Frederiksen)

Q. Dr. Frederiksen, how is it that uterine perforation occurs during a D&E in the second trimester?

A. Perforation is much more common with forcible dilatation of the uterus, but it can be an inadvertently happened when you are using forceps to grab tissue. There can be irregularities in the uterine wall which make you think there are fetal parts there and there are not. There can be irregularities in the thickness of the uterine wall, including with a scarred uterus, where you can very easily go through the scar, the prior scar, or have the scar open, and you then have a chance of delivering anything from the maternal abdomen.

[1058:10-1059:10] (Frederiksen)

Q. Doctor, you also testified that intact D&E can reduce the risk of cervical laceration. Why is that?

A. Cervical laceration can actually nick an internal branch of the cervical artery as well as lacerate the endocervical canal and cause bleeding. The leading cause for this is bony pieces, pieces of bony parts of the fetus which can be very sharp, and when you pull them through the cervix can lacerate the cervix and cause hemorrhage.

Q. What causes the presence of sharp bony parts in the first place?

A. The dismemberment process that is necessary to empty the uterus.

Q. Are these fragments present in an intact evacuation?

A. No, they are not.

Q. Why not?

A. Because the fetus is delivered almost or virtually intact, [1059] and thereby you don't have those bony fragments.

Q. Dr. Frederiksen, is there a high risk of cervical laceration or uterine perforation from bony fragments during a D&E?

A. If you end up having a situation where you end up having multiple fetal parts, there is always a risk of cervical laceration.

Q. Is that why you try to control for this risk?

A. We decrease that risk by doing an intact or near intact procedure.

[1060:8-1064:18] (Frederiksen)

Q. You testified that intact D&E can also produce the risk that fetal tissue or parts can remain behind in the uterus. How is it that fetal tissue or parts can remain behind doing an D&E?

A. If you do a D&E where the fetus doesn't come out intact, you are making an assumption or you make your best clinical estimation that the uterus is entirely empty. Unfortunately, we are not very good at that, and we can leave either fragments of the fetus in the uterus or fragments of the placenta in the uterus, and there can be a nidus for infection and there can be the cause of a post-abortal hemorrhage.

Q. Used the word "a nidus." What is that?

A. Like a focus.

Q. So it would be a location of, a point of infection?

A. Yes.

Q. What is post-abortal hemorrhage?

A. Post-abortal hemorrhage is hemorrhage which occurs after the abortion has occurred. It can be episodic or you can get a [1061] hemorrhage and then find no evidence for the bleeding by examining the patient. That is characteristic of a cervical artery laceration of the internal os or the inter-

nal os of the cervix, where bony fragments can lacerate that branch of the cervical artery.

Or they can be caused by the uterus failing to contract or maintain a contraction after the delivery of the fetus and the majority of the pregnancy. That is called uterine atony, and that may necessitate reexploration of the uterus or use of medications.

Q. Why are you concerned about the uterus failing to contract? What purpose does that serve?

A. The physiological changes of pregnancy increase the cardiac output proportion that goes to the uterus during pregnancy. That is maintained in the post-partum stage. So an obstetrical post-partum hemorrhage or a post-abortal hemorrhage—

THE COURT: Doctor, can you slow down a little bit?

The reporter has to get it all.

THE WITNESS: Yes.

A. I don't know where I was.

Q. I had asked you about why you were concerned about the uterus being able to contract after an abortion procedure.

A. During pregnancy a higher proportion of the cardiac output is directed to the uterus, and that is maintained in the post-pregnancy termination period, whether that be at 24 weeks [1062] or 22 weeks or 17 weeks. It takes approximately 12 weeks after pregnancy termination for the card cardiovascular changes to go back to normal.

During that period of time, if the uterus failed to contract, the contraction of the uterus stops the arterials from bleeding into the cavity of the uterus. Atony, or failure of the uterus to contract, increases the amount of blood flow which can then accumulate in the uterus and then be passed vaginally. So obstetrical hemorrhages post-abortion or post-delivery can be very heavy.

Q. So failure of the uterus to contract impedes stopping of the bleeding? Is that sort of a basic way to say that?

A. Yes.

Q. You talked about some of the complications from having retained fetal tissue or parts in the uterus. Can those complications affect future reproductive health?

A. When you develop an infection in the uterus, you can develop something called Asherman's syndrome. It is usually associated with multiple curettage of the endometrial tissue, and it is also usually thought to be associated with infection. So yes you can develop a condition in which you don't have menstrual periods because the lining of the uterus has been damaged.

There can also intrauterine synechiae. That is a big term. It is basically internal scar tissue which go from one [1063] side of the uterus to another side of the uterus, and therefore impede implantation and development of the subsequent pregnancy. You can also get infection that is so severe that you can get blockage of your tubes.

Q. Why is it that the intact D&E retains the risk of retaining fetal tissue or parts?

A. Ensuring that the fetus delivered intact or virtually intact decreases the chances that there can be amounts of tissue in the uterus that are left. Also, when you do an intact, D&E you usually get the placenta out as more of a discoid organ rather than in bits and pieces.

Q. Doctor, I apologize if I maybe didn't hear you. When I asked you why it is that fetal tissue or parts—let me start over. I apologize.

When I asked you why intact D&E reduces the risk of fetal tissue and parts remaining in the uterus, I think you said that intact D&E reduces the risk of fetal tissue or parts remaining in the uterus. I would like you to explain why that is.

A. Because the fetus comes out intact or virtually intact, there are no fetal pieces of tissue left within the uterus. As such, when you deliver the fetus intact or virtually intact, the placenta can come out also virtually intact, thereby ensuring that the uterus contracts and there is no retained

products of conception within the uterus, which is the leading [1064] cause of infection in the post-abortal period.

Q. Dr. Frederiksen, can you assure that all fetal tissue and parts have been removed by scanning with ultrasound following the procedure?

A. You can if you don't think that you haven't completed the procedure. Ultrasound is usually available to scan the patient. But then if you don't have an intact fetus or you are questioning whether the uterus is really empty or not, if you actually have some left, you have to go back and continue the procedure.

Q. Does that lengthen the procedure?

A. Yes.

Q. Can you always visualize remaining tissue with an ultrasound?

A. No, because you lose the contrast of the amniotic fluid as you empty the uterus, and fetal parts are the same density sometimes as blood clots. Therefore, you may not be able to see them.

[1065:6] (Frederiksen)

A. Intact D&E is a variation of D&E.

[1080:1-4] (Frederiksen)

A. A D&E in the second trimester is not usually associated with uterine rupture and is actually safer for a woman who has undergone a caesarian section or any classical incision on her uterus, or even a myomectomy.

APRIL 6, 2004

[1096:23-1097:3] (Baergen)

MS. STERNBERG: Your Honor, we tender Dr. Baergen as an expert in pathology and perinatal pathology pursuant to Federal Rule of Evidence 702.

[1097] MR. PANTOJA: No objection, your Honor.

THE COURT: The Doctor will be so recognized by the Court.

[1161:21-24] (Frederiksen)

Q. Dr. Frederiksen, is intact D&E the only technique available to terminate pregnancy in the second trimester?

A. It is not necessarily the only technique but it is the safest.

APRIL 7, 2004

[1311:1-1316:25] (Weiss)

Q. Dr. Weiss, do you currently treat patients?

A. I do.

Q. In what settings do you treat patients?

A. I treat patients in an office setting in New Jersey, in Hasbruck Heights, in an office called University Reproductive Associates. I also take patients who are in-patient both in Hackensack University Medical Center and University Hospital in Newark. I sometimes see patients in consultation with Newark as well.

Q. What type of patients do you see?

A. By and large, I take care of patients with problems in gynecology. I am frequently referred to complex problems from other gynecologists, and I see a full range of reproductive endocrinology and infertility cases as well.

Q. Do you perform surgery?

A. I do.

Q. How often do you perform surgery?

A. Roughly 50 times a year.

Q. What types of surgeries do you perform?

A. I perform a fairly broad gamut of surgery in gynecology and in my subspecialty. These include office surgical procedures as well as hospitalized procedures, including reparative procedures, endoscopies, laparoscopies, hysteroscopies, vaginal and abdominal hysterectomies.

Q. You mentioned hysteroscopies. Can you explain what those [1312] are.

A. A hysteroscopy is an operative procedure where the cervix is dilated and then the inside of the uterus is evaluated

with a telescope put into the uterus through the cervix. In doing so, we can diagnose the presence of fibroids that are impinging on the cavity, occasionally observe a malignancy, observe polyps, adhesions, scars, and anomalies and things that interfere with fertility. They can frequently be corrected at the same time through instruments put into the scope.

Q. You also mentioned laparotomies. Can you explain what that is.

A. A laparotomy is an operation where the abdomen is opened. It is a generic term for any time the abdomen is opened. Specifically in gynecology, laparotomies, hysterectomies, abdominal hysterectomies, removal of cysts, tubal repair, tubal ligation, or removal of ovarian cysts and other things that need to be done through an open incision.

Q. Have you ever performed an abortion?

A. Yes.

Q. Approximately how many times in your career have you performed an abortion?

A. Approximately 1500 to 2,000.

Q. What types of abortions have you performed?

A. I have performed D&C abortions, including both sharp curettage and dilatation and suction. I performed D&E [1313] procedures later on in pregnancy. I have performed an occasion hysterotomy. I have performed instillations. I think that completes it.

Q. Do you currently perform abortions?

A. I do.

Q. Dr. Weiss, how did you first learn to do abortions?

A. When I was a resident, abortions were not permitted and were illegal. When I was a chief resident in 1969 and the end of 1968, the law had softened somewhat in New York State and there was the ability to do abortions for women whose lives were endangered by the process.

Before that time, what we would see in my training at Bellevue Hospital were the referred complications of crimi-

nally induced abortions throughout the city. So every week, especially as a first-year resident, I would have to deal with completion of abortions of first and second trimester procedures, many times in women who had infected uteri and multiple problems. This is where I learned the techniques of finishing the abortion process, in dealing with the issues, in dealing with the complications and the trouble caused when procedures are not performed accurately and adequately.

When I was a chief resident, I had 12 individuals who, for medical or psychiatric reasons, were deemed by an independent committee of physicians and other members of the community that an abortion was appropriately required. These [1314] women were in their second trimester. Because the process was a long one and even if they presented at 8 weeks, which would be usual—because you could rarely in those days diagnose a pregnancy before 6 or 7 weeks—they would have to go through a committee and they would be in their second trimester.

Using the skills that I had developed as a junior resident dealing with the many hundreds of abortions that were in various stages of completion, I trained myself to perform these abortions, because no one had done them beforehand and there was no one that could teach the procedure. The skills are not that much different from the skills I already had. So I learned really in a way being self-taught at that time.

Q. What were some of the consequences of the illegal inabortions that you described?

MR. LANE: Objection, your Honor.

THE COURT: What, pray tell, has this got to do with this case?

MS. PARKER: Your Honor, may I?

THE COURT: Yes.

MS. PARKER: He is just describing the way he learned abortions and some of the consequences.

THE COURT: I think you are going far beyond that.

MS. PARKER: I will move on, your Honor.

THE COURT: Sustained.

Q. Dr. Weiss, approximately how many D&E procedures have you [1315] performed throughout your career?

A. I would estimate 20 percent of the total, so that would be somewhere around 3 to 500.

Q. In conjunction with your work at the hospital and the medical school, do you supervise other physicians' abortion practices?

A. Yes. I am required to do quality control for all procedures in the hospital. There was a period of time when the abortion service, for varying reasons, was actually not part of the obstetrics and gynecology department. But even at that time I was responsible for the oversight of the procedures, the quality assurance, and the evaluation of the procedures by morbidity and mortality conferences.

I now see that residents are trained in these procedures and evaluate the process. Specifically, we have generic screens, such as readmission to the hospital for removal of structures not planned for, readmission within a month after procedure, that trigger what is called the morbidity mortality conference, which is an evaluation of the problem, why it occurred, what could be done to prevent it from occurring again.

We have now established, I have hired someone to establish, an abortion service. She has received a national grant from the Ryan Foundation for I guess it is $450,000 the first year to set up training programs to teach individuals all [1316] aspects of contraception and abortion. This is to teach residents as well as medical students and other—

THE COURT: What foundation is this?

THE WITNESS: The Ryan Foundation.

THE COURT: How do you spell that?

THE WITNESS: R-Y-A-N. It is named after Kenneth Ryan, who was the chairman of obstetrics and gynecology at

Harvard Medical School for many years and the chairman of I believe it was President Nixon's ethics committee.

Q. Dr. Weiss, how many D&E procedures have you supervised your career?

A. It would have to be thousands.

Q. Are you familiar with a variation of the D&E procedure sometimes known as intact D&E?

A. Yes.

Q. Have you ever delivered a fetus intact in a D&E procedure that you have performed?

A. Yes.

Q. Do you have any responsibility for training other physicians?

A. Yes. Part of my job as the chairman of the medical school department is to see that we train other physicians in the subspecialty. We specifically through this grant are required as a department, as recipients of this, to train individuals as well.

[1321:10-16] (Weiss)

Q. Do you have an opinion regarding the safety of removing the fetus intact in a D&E procedure?

A. Yes, I do.

Q. What is that opinion?

A. My opinion is that removing the fetus intact is a safer procedure than disarticulating or breaking the fetus into parts before removing it.

[1322:25-1324:3] (Weiss)

Q. Doctor, you were describing why it is that you thought that [1323] removing the fetus intact in a D&E procedure was safer. Did you have more to add on that?

A. Yes. When the fetus comes out intact, there is minimal manipulation inside the uterus, hence minimal chance of producing damage. You see the entire fetus. If you were dismembering the fetus, what you would have to do is take

the parts, leave them aside, and then try to reconstruct the fetus from what you have done.

You can reconstruct in a general sense. You can find limbs, maybe trunk, maybe head. But there is the possibility that small parts or pieces of soft tissue would be left inside the uterus, and that could serve as a nidus of infection, and that can serve as a problem in the future in which retained-products would produce pain in the future, abnormal periods, or even, by functioning as a foreign body in the uterus, functioning as an intrauterine contraceptive device and therefore interfering with conception.

None of this will happen when you are doing an intact D&E. When you are doing an intact D&E, the entire procedure is under visual control. What you need to do is deflate the head, but you have much control over that and it is right in front of you at the time.

The time of procedure is decreased. It is clear, a vast medical literature suggests, that the complication of infection is highest the longer the procedure. During an [1324] abortion procedure there is bleeding until the procedure is completed. A briefer procedure results in less blood loss and less risk, again, of infection and leaving material behind.

[1330:25-1332:8] (Weiss)

Q. You mentioned that in a dismemberment procedure there is a [1331] risk to removing the fetal parts. Can you explain how an intact procedure would reduce those risks.

A. With an intact procedure, there would be no sharp parts, so there would be nothing to embed in the uterine wall or tear the cervix. In an intact procedure, you would not have the multiple insertions of equipment that would produce the potential of uterine rupture and/or uterine damage or the increased risk of infection as one did this procedure multiple times.

THE COURT: But both do occur in intact D&E's, do they not, from time to time?

THE WITNESS: At a lesser incidence—

THE COURT: But they do occur?

THE WITNESS: No, not all of them, sir. You would not leave fragments in the uterus.

THE COURT: I didn't say that. They do occur occasionally?

THE WITNESS: Excuse me. What do you mean by "they"? Which they?

THE COURT: Perforation of the uterus.

THE WITNESS: Perforation can occur.

THE COURT: And does infection occur?

THE WITNESS: It can occur.

THE COURT: That's all I asked, Doctor. Next question.

[1332] Q. Doctor, when you remove the fetus in a procedure involving dismemberment, are the fetus's bones covered by soft tissue?

A. Excuse me? When you?

Q. Remove the fetus in a dismemberment procedure, are the pieces of the fetus covered by soft tissue?

A. Frequently much of the bone is covered. It is quite likely that the ends of the bone in the area that is broken are uncovered and sharp.

[1335:18-1336:5] (Weiss)

Q. Dr. Weiss, would a D&E involving intact delivery offer any advantages over a D&E involving dismemberment for a woman with any kind of uterine scar?

A. The answer is yes. A woman with a uterine scar from surgery, let's say, that removed multiple fibroids may have very thin areas in the uterus which, with multiple insertions of equipment, potentially produce problems such as perforation. An intact removal is more straightforward, simple, and [1336] definitive.

If a woman had a Cesarean section scar, likewise, if it were a vertical scar, you would be at risk of having a thin area in the uterus and having it perforated. And more perforation is likely with multiple insertions of equipment.

[1338:2-1340:11] (Weiss)

Q. Does the fact that you can't think of a circumstance that would require intact D&E affect your opinion on the safety of it?

A. Not at all.

Q. Why not?

A. Because if you can't have it done for all of the reasons I have mentioned it would be a much safer procedure. Ergo with less risk of blood loss, less risk of damage to the uterus, less risk of infection—in all situations it would be preferable if it could occur.

Q. Doctor, you testified that in your own practice you have delivered the fetus intact in a D&E procedure, is that correct?

A. That's correct.

Q. Now, up to what week of gestation do you perform D&Es?

A. 18 weeks.

Q. Are you aware of a definition of intact D&X that's been set forth by the American College of Obstetricians and Gynecologists?

A. Yes, I am.

Q. Is the ACOG definition that you are aware of a four-part definition?

A. Yes.

Q. Is it a definition that says: One, deliberate dilation of the cervix usually over a sequence of days; two, instrumental [1339] conversion of the fetus to a footling breech; three, breech extraction of the body excepting the head, and; four, partial evacuation of the intercranial consents of a living fetus to effect delivery of a dead but otherwise intact fetus?

A. Yes.

Q. That's the definition you are aware of?

A. Yes.

Q. Do you perform intact D&X procedures as described by ACOG?

A. I do not.

Q. Why is that?

A. I do not because that would usually be done beyond 18 weeks and I do not perform procedures beyond 18 weeks.

Q. I would like to read you another definition of intact D&E, this is a definition from Plaintiffs' complaint: "Intact D&E, which is also known as intact dilation and extraction or D&X is one variation of the D&E procedure, generally used after 19 weeks' LMP that is intended to maximize the chances of an intact or relatively intact delivery and thereby minimize risk to the woman." Are you familiar with that definition?

A. Yes.

Q. Do you perform intact D&E as described in that definition?

A. I do not.

Q. What is different about your practice in that definition?

A. I only perform procedures up to 18 weeks.

[1340] THE COURT: Why is that, Doctor?

THE WITNESS: Well, I have only been trained and had experience in doing them in 18 weeks. These are relatively or quite rare procedures, so my feeling is that if I'm going to do them without an experience behind me, I would not want to do it rarely and would prefer to refer the patient to someone with greater expertise who has a greater learning curve with it because they have done more procedures.

THE COURT: How long have you done the intact D&Es up to 18 weeks?

THE WITNESS: I have done them since 1973.

[1341:7-21] (Weiss)

Q. Dr. Weiss, you testified earlier that you only performed procedures up to 18 weeks, is that right?

A. That's correct.

Q. And you also testified that you have brought a fetus out intact in some of the D&E procedures that you have performed, is that right?

A. That's correct.

Q. Is your ability to bring the fetus out intact affected by the fetal tissue at that gestational age that you perform D&Es?

A. The earlier the pregnancy the more fragile the fetus. So, grasping a fetus early on is more likely to tear it and less likely to allow you to bring it out whole. If the fetus were older its condition would be tougher enough that it could take, you could move it into an appropriate position easier.

[1345:23-1346:2] (Weiss)

A. Well, all medical procedures produce risk. You need to look at the risk of a pregnancy termination in comparison to the other methods available at **[1346]** that time. In fact, an intact D&E poses less risk than any other method.

[1363:21-1364:1] (Weiss)

A. Your purpose in doing the procedure is overall to terminate the pregnancy, to make the woman no longer pregnant. You want to do this in as atraumatic a way as possible to the mother. Hence, in removing the fetus longitudinally, one has atraumatically removed most of the fetus. This is safer for **[1364]** the mother but would come into conflict with the Act.

[1421:2-12] (Weiss)

Q. Dr. Weiss, how do the risks of the intact D&E procedure, as defined by ACOG, compare to the risks of a dismemberment D&E?

A. The risks of the intact procedure are less. They're less because it's a faster procedure with potentially less blood loss because it's faster with less risk of recurrent instrumentation and with less likelihood of leaving retained fragments.

Whatever one does when one pulls a fetus apart, one can never be sure that you haven't left pieces behind, some of which are stuck in the wall of the uterus and you would be unable to get them out.

[1439:1-6] (Paul)

"Q. What would be some of the other circumstances in which a physician might use an intact D&E?

"A. I perform an intact D&E whenever I can, whenever cervical dilation is sufficient for me to extract the fetus intact, because I believe it's safer than a D&E which requires several instrument passes.

[1441:10-16] (Paul)

"Q. You've mention that had in doing a D&E procedure it's preferable to have the fetus delivered as intact as possible. Can you tell me why that is.

"A. I believe it's safer because there's fewer instrument passes and because I know that I've extracted the whole fetus, and so the risk of having retained fetal parts or retained tissue is virtually eliminated.

[1445:10-21] (Paul)

"Q. I'm turning your attention to the second sentence. I will read that. It says, 'The Act thus denies physicians the necessary discretion to provide medical care with the safety and health of their patients as their foremost concern.' In your experience, was there ever a situation in which an intact D&E was necessary to preserve the life or health of the mother?

"A. I think in terms of preserving health, it's really synonymous to say that you're using the safest method possible. And so, yes, in my experience, when I perform an intact D&E, I do think that it is preserving the health of the mother, because I believe it to be the safest way to proceed at that time.

[1450:8-10] (Paul)

"A. It didn't make the distinction. Because intact D&E is a variant of D&E, it may have included some cases of intact. I don't know. It didn't address that in the article.

[1451:9-1452:9] (Paul)

"Q. I'm sorry. I misspoke. It's Paul Exhibit 3. If I could turn your attention to page 4, paragraph 19. The first sentence reads, 'The absence of controlled studies involving D&E's in which the fetus is removed intact or largely intact

does not cast doubt on the safety of such abortions.' Do you agree with that statement categorically?

"A. Categorically. I generally agree with that statement, that's right.

"Q. When you say generally agree with that statement, what do you mean by that?

"A. That there are good studies that show the safety of D&E abortion, and it's my opinion that intact D&E is a variant of D&E abortion in that in fact many of the studies that were probably done in the past included cases of intact. I don't think it's necessarily true that those studies had to have mentioned intact as a separate entity, because I regard it, and I think many physicians regard it, as just a variant. So I do, **[1452]** I do believe that there probably has been more research than is credited on the technique.

"And I think in the—if you look at evidence-based medicine, that one of the tenets of evidence-based medicine is that if there are no studies, no evidence that actually proves that a specific procedure is superior to another procedure, then it's at the discretion of the physician to use whatever option he or she believes is safest and best to use in those circumstances. And in my experience, intact D&E is safer.

"Q. Dr. Paul, in a D&E procedure in which disarticulation or dismemberment occurs, how does the disarticulation or dismemberment, how does that take place?

"A. It takes place by extracting a fetal part, which generally causes counterpressure at the internal os of the cervix, at which point the piece will disarticulate."

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[1503:11-1504:2] (Creinin)

"A. As the—when I do the procedure, when I am pulling the fetus through the, the fetal part, I have a grasp of, through the cervix as it is coming through the cervix. If it gets to a point where I am meeting resistance then I will begin to gently rotate minimally as it is working through the cervix

but not twist. Again, just twisting minimally. And, no, you can't put this into words, but just twisting minimally.

"Q. What is the purpose of twisting minimally?

"A. To ease the part through the cervix because there is—you are meeting resistance from the cervix so I don't want to yank very hard to tear the cervix. I want to allow the cervix, allow that part to work through the cervix and have the resistance from the lower uterine segment and the internal os, allow the fetus to break apart if it is going to do so.

"As I stated earlier, my goal is to attempt to remove [1504] the fetus as intact as possible, to have as few parts for the safety of the patient."

[1551:12-1555:13] (Chasen)

Q. Do you perform surgery, Dr. Chasen?

A. Yes, I do.

Q. What types do you perform?

A. Surgical procedures. I perform Cesarean delivery, which is when a baby is delivered through an incision in the uterus and the maternal abdomen. I perform procedures in women who are pregnant, and these include something called a cervical cerclage, which is a stitch tied around the cervix. This is done with the intent of preventing preterm birth. And in some women I also perform abortions.

Q. Approximately how many times in your career have you performed abortions?

A. In my career, probably, including first and second rimester, I would estimate about 500.

[1552] Q. How does that divide as between first and second trimester?

A. I think the first trimester abortions, and most of these I did during my residency, were probably 50 percent of it, and the rest would be second trimester.

Q. Does the number you just supplied include surgical treatment or management of spontaneous abortion?

A. Yes, it does include that.

Q. Approximately how many abortions have you performed or supervised over the past year, Dr. Chasen?

A. About 50.

Q. How many of those were second trimester?

A. Over the last year, all of them.

Q. What type of abortions have you performed?

A. I have performed abortions using suction curettage. Typically, these are before 14 weeks of gestation. And I perform surgical abortion with dilation and evacuation in which the cervix, unless it is a woman that has a form of preterm labor miscarriage who spontaneously dilates her cervix. Dilation and evacuation involves placing laminaria in the cervix and then evacuating the fetus and the placenta from the cervix one or two days later typically.

Q. Have you performed second trimester induction abortions, Doctor?

A. I have, yes.

Q. You testified about your abortion procedures performed over [1553] the past year. Currently, what type of abortion procedures are you performing?

A. Surgical abortions.

Q. Are those second trimester abortions?

A. Yes. Over the last year, D&E is the only procedure I have done over the last year.

Q. Give us the range with respect to gestational age of the area in which and the time in which you performed second trimester surgical abortions.

A. With the exception of cases of fetal demise, which may exceed 24 weeks, these are all from 13 weeks to 23 weeks and 6 days.

Q. When you say with the exception of fetal demise, do you refer to situations in which there has been fetal demise prior to the performance of any surgical procedure?

A. Yes, spontaneous fetal demise or what some would call stillbirth.

Q. Did you have any training in abortion procedure or practice, Dr. Chasen?

A. Yes, I did.

Q. Can you describe that training for us, please.

A. During my residency I was trained in techniques of first trimester abortion going up to about 12 weeks and using suction curettage, which is a form akin to vacuum aspiration. That was during my residency. I had very minimal exposure and just [1554] observation of second semester surgical abortion with D&E.

THE COURT: What year was that, Doctor?

THE WITNESS: My residency was between 1992 and 1996.

A. Starting in my fellowship when I came to the New York Hospital in 1996, I received training in performing dilation and evacuation, the form of surgical abortion in the second trimester.

Q. Are you familiar with a variation of D&E procedure known as intact dilation and evacuation, or intact D&E?

A. Yes, I am.

Q. Have you heard that procedure referred to by any other name, Dr. Chasen?

A. I have. I have heard it referred to as, besides "intact D&E," "intact dilation and extraction" or "intact D&X" or just "D&X," and "partial-birth abortion."

Q. Is "partial-birth abortion" a medical term?

A. No, it is not.

THE COURT: Is this a convenient time to take our morning recess, Mr. Hut? Or do you have some line that you wish to continue for a short time?

MR. HUT: No. This will be a fine time, your Honor.

THE COURT: We take our recess.

(Recess)

THE COURT: Mr. Hut, you may inquire.

MR. HUT: Thank you, your Honor.

[1555] BY MR. HUT:

Q. Dr. Chasen, approximately how many D&E procedures have you performed during your career?

A. Between 200 and 300 by my estimation.

Q. Have you ever performed an intact D&E, Doctor?

A. Yes, I have.

Q. Approximately how many times?

A. I would estimate between 50 and 75.

Q. Do you perform intact D&E as a part of your regular practice, Dr. Chasen?

A. Part of my regular practice does include performing second trimester surgical abortion, and as a part of my regular practice I do that procedure in some cases.

[1572:19-1574:4] (Chasen)

And when forceps are involved, in most cases disarticulation or dismemberment of the fetus will occur in the process of removing the fetus from the uterus although, in some cases, the fetus may come out intact using forceps or intact at least to the level of the head. But, in some cases, intact entirely.

If I make the determination that the cervical dilation [1573] and the proximity of the cervix to the vagina and the fetal position would enable me to do a breech extraction, then I will deliver the fetus like that and this will involve either manually, with my hands, bringing one or both of the legs through the cervix into the vagina, proceeding with a breech extraction.

And, in most cases, the degree of cervical dilation will not accommodate passage of the fetal head through the cervix. And in this case my practice is to make an incision at the base of the skull with the scissors, which I can do really under direct visualization, place a suction device within the skull, the brain tissue is aspirated and, typically, the head then delivers easily.

Q. And what do you do in the event that you are not able to—

THE COURT: Excuse me. Does that mean because the skull collapsed?

THE WITNESS: Yes.

THE COURT: That it delivers easily?

THE WITNESS: Once the skull has collapsed.

THE COURT: Okay. Go ahead, Mr. Hut.

BY MR. HUT:

Q. When you are not able to achieve a breech extraction and a relatively intact extraction, how do you evacuate the uterus in a D&E?

[1574] A. Again, in most cases this requires multiple insertion of forceps which will grasp parts of the fetus and in most, but not all cases, involve dismemberment of the fetus and removal from the uterus in parts.

[1584:22-1585:9] (Chasen)

Would D&E present the same concern that uterine rupture for a woman with a classical c-section scar or scarring from myomectomy would?

A. D&E would not expose the patient to that degree of risk.

[1585] Q. Why not, Dr. Chasen?

A. The risk relates to contractions in the muscle of the uterus and D&E is, involves mechanical—involves dilation of the cervix through laminaria, not through inducing contractions in the uterus.

Removing the fetus through whichever technique of D&E does not involve expulsion with contractions of the uterus, thus it avoids the stimulation of the muscle of the uterus which is what precedes uterine rupture.

[1588:23-1589:5] (Chasen)

Q. Dr. Chasen, do you have an opinion regarding the safety of intact D&E as compared to dismemberment D&E?

A. Yes, I do have an opinion.

[1589] Q. What is your opinion, Doctor?

A. My opinion is that in patients in whom I am able to do a D&E with intact extraction, that this procedure – this varia-

tion of D&E offers safety advantages compared to dismemberment.

[1590:1-17] (Chasen)

Q. Doctor, returning to your opinion concerning the safety of intact D&E, why can intact D&E be the safest way to perform a D&E?

A. Based on my experience, complications of D&E relate to insertion of instruments, typically forceps into the uterine cavity.

Insertion of forceps in the course of dismembering the fetus and removing it, every time the forcep clasps around some tissue, even under ultrasound guidance, I can't be certain that it's not grasping maternal tissue, the uterine wall. So, use of forceps, and again these are used extensively in dismemberment, would increase the risk of uterine perforation.

In D&E using disarticulation or dismemberment, portions of the fetal skeleton are exposed and they may be sharp edges and removing these through the cervix may expose the cervix to trauma.

[1590:21-24] (Chasen)

Q. As between intact D&E and dismemberment D&E which, if either, poses a greater risk of retained fetal tissue?

A. Using D&E with dismemberment poses a greater risk of retained fetal tissue.

[1592:9-15] (Chasen)

Q. What causes the presence of bony fetal parts about which you testified earlier?

A. Fetal dismemberment with forceps would cause exposure of bony fetal parts.

Q. Do bony fetal parts present any risk of cervical laceration, in your opinion?

A. In my opinion they do.

[1593:2-9] (Chasen)

Q. Why does intact D&E reduce the risk of retained fetal tissue, Dr. Chasen?

A. In delivering the fetus intact to the level of the head and then in suctioning out the brain tissue through a small incision at the base of the skull and then removing the fetus, I can clearly identify that all fetal tissue has been removed and that there is 100 percent no chance of any remaining fetal tissue.

[1611:11-1612:12] (Chasen)

Q. Dr. Chasen, when you set out to perform an abortion, can you assure that the D&E that you perform will proceed intact?

A. No, I can't.

Q. How, then, can you say that the procedure offers advantages?

A. In some cases, in the cases in which I am able to do it based on cervical dilatation, proximity of the cervix to the vaginal opening and fetal position, it offers safety advantages. These women are typically at a more advanced gestational age.

If I could do it with intact extraction, then I could do it without introducing forceps into the uterine cavity, which increases the risk of trauma to the uterus, including rupture, and I can remove the fetus without exposing the maternal tissues to sharp edges of bony fragments and I believe **[1612]** I can minimize the risk of hemorrhage and shorten the procedure time.

Q. Dr. Chasen, in your opinion, is an intact D&E ever the only available procedure to terminate a second trimester pregnancy?

A. No.

Q. Does this affect your view of the safety advantages with intact D&E?

A. No, it does not.

Q. Why not?

A. In the cases in which I can do it, I have sufficient cervical dilation and the other factors I have mentioned, I am doing it because that is the way I can remove the fetus.

[1612:22-1614:13] (Chasen)

Q. Dr. Chasen, please turn in the notebook that I have supplied to you to tab 23A. Doctor, do you recognize Plaintiffs' Trial Exhibit 23A?

A. Yes, I do.

[1613] Q. What is it?

A. This is an article accepted for publication in the American Journal of Obstetrics and Gynecology. These are the proofs of that article, entitled "Dilation and Evacuation at Greater Than or Equal to 20 Weeks: Comparison of Operative Techniques," and I am the primary author of the study.

Q. Please put that aside for the moment. You said it has been accepted for publication. Do you know when it is scheduled for publication?

A. It is scheduled for publication in May of this year.

Q. I think you mentioned this before, but remind us again. Is the American Journal of Obstetrics and Gynecology a peer-reviewed publication?

A. It is a peer-reviewed publication.

Q. What did you and your co-author set out to do in the study that is described in Plaintiffs' Trial Exhibit 23A?

A. Our objective was to describe a large series of patients who have had a D&E at 20 weeks or beyond and to look at the characteristics of patients and compare the outcomes based on which variation of D&E was used.

Q. Did the study as you performed it make such a comparison?

A. Yes, it did.

Q. Whose idea was it, Dr. Chasen, to conduct the study reflected in Plaintiffs' Trial Exhibit 23A?

A. It was my idea.

[1614] Q. Why did you do it?

A. I did it because any time I take a study, any time I perform a study, including everything I have published prior to this, the objective is to answer a question. There are very few resolved issues in medicine, and there are very many questions, and sometimes there is no data addressing a question and sometimes there is conflicting data. As a physician in academic medicine, if you have data that can address one of these controversies, I think it behooves you to collect your data and publish it.

Q. Were there any preexisting published data addressing the comparisons that you and your co-authors made in the study?

A. Not that I am aware of.

[1625:21-1631:9] (Chasen)

Q. In your opinion, Dr. Chasen, was the methodology and the data you used appropriate to draw reliable conclusions about the respective safety of the two techniques of D&E?

A. Yes, I do believe that.

Q. In particular, do you think the number of cases studied was **[1626]** sufficient?

A. Yes, I do.

Q. Why is that?

A. In looking at the medical literature published before this, especially from single institutions, a series of 383 of these cases constitutes a very large series. To our knowledge, there is no prior data looking at techniques, including the intact extraction. In the midst of controversy about this procedure and in the absence of any prior published data, I think this is an important study; and I think, given the size, the data and our conclusions are reliable.

Q. Doctor, what were your results regarding the comparative complication rates of intact D&E and D&E with dismemberment?

A. Out of the 383 patients, 19 patients had complications. It was 5 percent overall and it was 5 percent in each group, in the D&E with intact extraction and the D&E with disarticu-

lation. Looking at the two groups and nothing else, the complication rates were identical.

Q. What does a complication rate of 5 percent overall and within the two groups reveal about both these abortion variations?

A. That as we perform them in our hospital, they are safe, especially given that the majority of complications we would consider minor.

Q. What kind of complications did you observe in your study?

[1627] A. I think a majority of the complications were genital tract lacerations, mostly cervical lacerations, superficial lacerations where the clamp was put on the cervix that required sutures. There was at least one patient that had severe nausea from presumably anesthesia that required an unplanned admission to the hospital. There were one or two patients who went home and then had to come back to the hospital for bleeding who were found to have retained tissue and had to undergo suction curettage procedure subsequent to that.

There were three complications that we considered major, because three patients required admission to the intensive care unit. One of these patients had a uterine perforation and required hysterectomy as well as blood transfusion. Another patient had an amniotic fluid embolus, and she required admission to the intensive care unit and transfusion of blood and blood products.

The third of these patients had a bodywide infection called sepsis and a pulmonary embolus, which is when the blood clot lodges in the blood vessels in the lung, both of which are life-threatening conditions, and she was admitted to the intensive care unit as well.

Q. Just briefly, what is amniotic fluid embolus?

A. Amniotic fluid embolus is when a portion of amniotic fluid leaves the uterine cavity and enters the circulation, the blood vessels of the mother. This can induce what we think is like a [1628] severe allergic reaction throughout the body,

particularly in the blood vessels in the lungs. This could cause essentially a collapse of blood pressure. The most common outcome of amniotic fluid embolus is death.

Q. Did any of what you described as these three major complications occur in the group of patients who had had intact D&E?

A. None of these complications happened in those patients.

Q. Did you find that the difference between the two groups in terms of the major complications was at a level of statistical significance?

A. It was not.

Q. Were there any differences, Dr. Chasen, in the demographics of the studies to cohorts?

A. There were differences.

Q. What were those?

A. I think the most significant difference is that the median gestational ages, the women who had D&E with intact extraction were closer to 23 and 24 weeks as a whole group, and the women that had D&E with disarticulation or dismemberment were more likely to be closer to 20 and 21 weeks. So as a whole the women with the intact extraction variation, that group were of more advanced gestation, with bigger fetuses and more placental tissue. That was one difference.

Q. Let me interrupt you. Why, in your judgment, is that [1629] difference in demographics a significant one?

A. It is significant because the rate of complications, and indeed the rate of maternal death, related to abortion in studies clearly demonstrates an increased risk with advancing gestational age. Complication rates are also higher with advancing gestational age. So the fact that women who had D&E with intact extraction were as a whole at more advanced gestation suggests that they were at higher risk for complications. They were at higher risk for complications.

Q. Dr. Chasen, were there any differences in the intraoperative variables as between the intact D&E cohort and the cohort for D&E with dismemberment?

A. We did not observe a difference in operative times or in estimated blood loss between the two groups.

Q. How about with respect to laminaria use?

A. There were more women in the D&E with intact extraction who were undergoing this procedure because they had dilated their cervix prematurely and were terminating, because they were at high risk of miscarrying prior to viability or shortly thereafter, and after counseling they chose to terminate.

These women who had advanced degrees of cervical dilation already did not require laminaria for cervical dilation before evacuation. And in that advanced degrees of dilation facilitate intact extraction, there were more of these women proportionally speaking in the intact extraction group [1630] compared to the disarticulation group.

Q. Dr. Chasen, did your study find a difference in the obstetric outcomes of subsequent pregnancies between the intact D&E cohort and the D&E with disarticulation cohort?

A. There were no significant differences between the two groups.

Q. What were the results?

A. I believe there were 4 patients who in a subsequent pregnancy were hospital-delivered prematurely, which is more than three weeks from the anticipated due date. 2 of these patients were in each group. It was 2 out of 45, which is between 4 and 5 percent, in the disarticulation group; 2 out of 17, which is 11 or 12 percent, in the intact extraction group. That was not a statistically significant difference.

Q. With respect to subsequent pregnancy outcomes, what is the import of the results that you discerned?

A. The two women who delivered prematurely following D&E with intact extraction were both women that had undergone abortion because they had ruptured membranes or

had considerable dilation of their cervix as the indication for undergoing an abortion procedure. These women, based on their obstetric history, were at very high risk of premature delivery, and did deliver prematurely following pregnancy, one at 32 weeks and one at 35 weeks. In light of their risk factors, these were considered very successful pregnancies.

[1631] It is important that in the 15 patients who underwent D&E and intact extraction who were not doing this procedure because they had ruptured membranes or had cervical dilation, in other words, who would not have had an obstetric risk factor for premature delivery following pregnancy, all 15 of these patients subsequently delivered at term. So in this group of patients it did not seem that D&E with intact extraction was associated—was not associated with subsequent preterm birth at all.

[1632:3-1633:4] (Chasen)

Q. Dr. Chasen, what was the conclusion in your study as to the relative safety of the two variations of D&E analyzed?

A. Our main conclusion was based on the data, based on the fact that the complication rates essentially were identical. They were both 5 percent. Or one was 4.9 percent and one was 5 percent. In our institution women undergoing D&E at these gestational ages, there was no difference—the complication rates between women undergoing the two procedures was comparable.

Q. Do you still adhere to that conclusion?

A. I adhere to the conclusion that both variations are safe and that there is a low complication rate, especially of major complications, for both procedures. However, given that I would consider the women who had D&E with intact extraction to be at higher risk for complications in that they were at more advanced gestational ages, with larger fetuses, with more placental volume, and more of these women had ruptured membranes or cervical dilation, which can be associated with a preexisting infection, which can be associated with hemorrhage, for instance, that this was a higher risk group for complications, the fact that we achieved the same

level, the same rate of complications in these two groups, who I don't think I would consider at equal risk of complications—and in [1633] fact we did not see any severe complications in the patients with intact extraction—in my opinion, we could take it a step further and say this is consistent with our belief that D&E with intact extraction has safety advantages.

[1634:3-16] (Chasen)

Q. I wondered whether there were other results in the study that support that conclusion to which you just testified.

A. Other than complication rates, in terms of achieving similar procedure times and similar blood loss, again, that indicates that if you have equal results in those intraoperative factors but you have one group—generally, procedure times in my experience relate to gestational age and how much fetal and placental tissue needs to be removed. How long it takes for the uterus to contract down and stop bleeding can depend on the size of the uterus at the outset of the procedure. And advanced gestational age of the uterus is bigger. Again, with equal operative times and equal blood loss, that suggests to me that there are safety advantages to D&E with intact extraction.

[1679:12-1691:8] (Chasen)

Q. You testified this morning in response to counsel's questions that in your opinion intact D&E is the safest way to perform an abortion as compared to dismemberment D&E, right?

A. When I can technically accomplish—if I can do either, the intact variation is safer.

Q. Your study doesn't support that conclusion, does it, Doctor?

A. I think my study does support that conclusion.

Q. You testified that in your opinion the intact D&E has safety advantages over D&E by dismemberment because the procedure is quicker, right?

A. Yes.

Q. Your study doesn't support that conclusion either, does it?

A. I don't think my data are inconsistent with that [1680] conclusion.

Q. Procedure time was the same, wasn't it?

A. It was the same, but in those cases with intact extraction, that group, based on appropriate statistical tests with which the reviewers and editors agreed, were at higher gestational ages as a whole than women who had D&E with disarticulation.

Q. You testified that the intact D&E has safety advantages over D&E by dismemberment because there is less blood loss with the procedure, correct?

A. Correct.

Q. Your study doesn't support that conclusion either, does it; the blood loss is the same?

A. When it is the same in two cohorts, one of which is in my opinion at considerably higher risk of hemorrhage, then it does support that safety advantage of D&E with intact extraction.

Q. 80 percent of the blood loss occurs after the placenta has been delivered, which is after the fetus has been removed from the woman, correct?

A. Correct.

Q. That is not blood loss from perforations or lacerations, is it?

A. It's not.

Q. Wouldn't you agree that you would expect that if there was a benefit to less passes with instruments, you would have less procedure time or less blood loss with intact D&E?

[1681] A. Yes.

Q. Your study doesn't show that you do, does it?

A. Again, the cohort in which we used the intact extraction and achieved the same blood loss in the same operative time

would be expected based on advanced gestational age to have increased operative time and increased blood loss. So, again, I think those safety advantages are not inconsistent with the data in the study.

[1694:18-1695:17] (Chasen)

With respect to your answer that for each gestational week there were various spreads of procedures done intact and procedures done by dismemberment, and your answer that those were apples and oranges, what did you mean by that?

A. In the whole cohort of 383 patients undergoing D&E at 20 weeks and beyond, the intact extraction variation of D&E was used in 120 cases, roughly about 30 percent. At 20 and 21 weeks, certainly at 20 and 21 weeks, the rate of intact [1695] extraction at those gestational ages was considerably lower than 30 percent. Starting at 22 and 23 weeks and 24 weeks, it was considerably higher than 30 percent.

To imply or to state with near statistical certainty that the gestational age distribution in the cohort that underwent intact extraction is at an increased gestational age then compared to the group that had D&E with dismemberment is not the same to say that it constituted a majority of cases at higher gestational ages. That is the apple and the orange, the majority versus the increasing proportion, the trend towards increasing proportion that we saw as gestational age advanced.

Those proportions and the statement comparing the gestational ages in the two groups were in the paper in the original version. It underwent peer review at two medical journals by six different peer reviewers and by two editorial boards, and none of them objected to that statement, because it was obvious.

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[1765:21-1766:1] (Lockwood)

Q. Does the fact that there may be less passes with instruments with D&X than there are with D&E by dismember-

ment affect your opinion that D&X does not have safety advantages over D&E by dismemberment?

A. I think I made it clear in the deposition that having fewer [1766] passes is certainly a good thing.

[1769:3-4] (Lockwood)

Q. Are there risks of retained placental fragment with D&X?

A. Presumably lower than with D&E.

[1788:25-1789:21] (Lockwood)

Q. Doctor, it is true, isn't it, that in your career you have [1789] never performed an abortion on a living fetus?

A. Correct.

Q. In fact, as a matter of policy, you do not perform abortions, based on personal philosophical reasons?

A. Right.

Q. You have performed suction curettage procedures on patients who suffered miscarriages, is that right?

A. Correct.

Q. And performed dilation in connection with that procedure?

A. Correct.

Q. But even to treat miscarriage, you have only rarely performed other methods of abortion, correct?

A. D&E's, for example?

Q. For example, yes.

A. Correct.

Q. You have performed a DEA on more than one occasion on a fetus that has already died following a miscarriage, true?

A. Correct.

Q. But you wouldn't claim as a result of that to have expertise in performing D&E's, would you?

A. No.

[1794:4-1795:8] (Lockwood)

Q. You were chair of the OB-GYN department at NYU for seven or eight years, from 1995 to 2002, correct?

A. Seven years, correct.

Q. As chair, you hired physicians who performed, taught, and supervised abortions, right?

A. Correct.

Q. As we have discussed, you hired doctors to direct the NYU reproductive choice program?

A. Correct.

Q. At least one of those doctors performed intact D&E procedures herself, right?

A. Correct.

Q. As to the other doctor that you hired, you just don't know if that doctor performed intact D&E procedures while she was there, correct?

A. That's correct.

Q. You relied on these doctors, Dr. Lockwood, to exercise their judgment in deciding what kinds of abortions to perform, correct?

A. Correct.

Q. They were trusted colleagues of yours, correct?

A. Correct.

[1795] Q. You gave them wide latitude to do D&E's, correct?

A. Correct.

Q. And wide latitude to train residents in doing them, correct?

A. Correct.

Q. You relied on them to determine what abortion procedures and variations to teach, right?

A. Correct.

[1817:24-1818:8] (Lockwood)

Q. There are certain women, Doctor, for whom you would agree inductions are relatively contraindicated, correct?

[1818] A. Correct.

Q. For example, you would agree that there might be an advantages to performing a surgical abortion and not an induction on a woman who had had a previous C-section, correct?

A. Correct.

Q. Or who had had scarring from other uterine surgery, correct?

A. Correct.

[1818:19-22] (Lockwood)

Q. The risk of uterine rupture in a patient that has had a previous Cesarean section is not present to the same degree in a surgical abortion, is it, Doctor?

A. Correct.

[1822:12-1823:1] (Lockwood)

Q. By the way, Doctor, are you aware of any randomized controlled studies showing any greater safety advantage to medical abortion over surgical abortion after 20 weeks LMP?

A. Not specifically after 20 weeks.

Q. It is your view, Doctor, that the theoretical benefit to the D&X is fewer manipulations inside the uterus, correct?

A. Correct.

Q. That might reduce the risk of perforation, right?

A. Correct.

Q. By fewer manipulations, you mean fewer passes of instruments in the uterus, right?

A. Correct.

Q. And fewer passes of instruments also means less risk of uterine perforation, correct?

[1823] A. It should.

[1823:14-1824:6] (Lockwood)

Q. Do you recall giving the following testimony in Nebraska at page 1712/line 21:

"Q. What do you see, Doctor, as the potential risks of a D&X procedure, both long and short term?

"A. Well, short term they would be identical to those of D&E. I think the theoretical benefit of an intact D&E is fewer manipulations, which might reduce the risks of perforation. Risk of perforation is not insubstantial. It can be as high in some studies as 1.4 percent, in others as low as .2 percent, but it is the most feared complication. So that I think is the great appeal of the procedure. So that's at least a theoretical advantage, the second part of your question was." [1824] Were you asked that question and did you give that answer, Doctor?

A. I would answer the same way today.

Q. You would therefore answer that perforation is indeed the most feared complication during D&E, is that correct?

A. Without a doubt.

[1825:9-1826:9] (Lockwood)

Q. You would agree, Dr. Lockwood, would you not, that fewer passes with instruments also reduces the risk of infection?

A. True.

Q. Given those risks from instrument passes, you would agree that in any D&E, including by dismemberment, it is medically appropriate to try to make as few passes into the uterus or cervix as possible, correct?

A. I would agree, as I did in deposition.

Q. In a D&X procedure, the uterus and cervix are also less likely to be exposed to sharp fetal bone and skull fragments, correct?

A. Correct.

Q. You would agree, Dr. Lockwood, that, all other things equal, the shorter the surgical procedure, the better for a patient, correct?

A. Always.

Q. All things equal, a shorter procedure carries less risk of [1826] bleeding, correct?

A. It may. It depends on what the two procedures are, I would say. But certainly I think that the operative time, if operative time is reduced, you would expect less risk of infection and perhaps less risk of bleeding.

Q. And perhaps less risk of trauma, correct?

A. Again, it depends on the procedures.

Q. A shorter exposure to anesthesia, correct?

A. For sure.

[1826:16-1827:20] (Lockwood)

Q. If a woman's uterus, Dr. Lockwood, is infected because of chorioamnionitis, the uterine wall may be damaged and thinned, correct?

A. Potentially.

[1827] BY MR. HUT:

Q. And there may, in this circumstance, be a theoretical advantage to minimum numbers of passes when the uterine wall is damaged and thin, right?

A. Correct.

Q. So there may be an advantage to D&X if a woman has chorioamnionitis, correct?

A. Medical abortion might be an equally attractive alternative, however.

Q. Can a woman with prior uterine scarring from c-section contract chorioamnionitis?

A. She can.

Q. And induction would be relative or absolutely contraindicated for such a woman, correct?

A. Correct.

Q. And a surgical abortion would therefore be preferable, right?

A. Correct.

[1828:4-14] (Lockwood)

Q. You acknowledge, don't you, Doctor, that there are intuitive or theoretical advantages to intact D&E?

A. Certainly the ones you've described.

Q. And in fact you use a somewhat intuitive process to decide when a pregnancy termination may be safest for your patients, don't you?

A. We usually call it delivery, but yes.

Q. So intuition has a role to play when knowledgeable physicians consider what steps might be preferable for their patients, doesn't it?

A. Certainly part of our clinical decision making.

[1831:18-1832:10] (Lockwood)

Q. In your expert report you also state that in order to quantify the risk of amniotic fluid embolism from abortion procedures from a meaningful statistical point of view you have to examine between 50,000 and a hundred thousand abortion procedures, correct?

A. At least.

Q. And you do not point to any study that is ever undertaken to do that, do you?

[1832] A. I don't think that there will be one and I don't think, frankly, given the rarity of the event, that it would be needed.

Q. So, you can't posit any increased risk of amniotic fluid embolism from use of the intact D&E procedure, can you?

A. No.

Q. Whatever risk there may be is no different than the small risk of amniotic fluid embolism from dismemberment D&E as you earlier stated it, correct?

A. Shrug—sorry. Yes.

[1849:23-1850:3] (Lockwood)

I think that my sense is that their goal really is to minimize the number of passes and if it, they can do it with a single pass, they'll do that. If it requires multiple **[1850]** disarticulations, they'll do that. But I do agree with the plaintiffs that the goal is to minimize the number of passes of instruments.

[1877:22-1878:18] (Lockwood)

Q. In December, before you spoke with counsel for the government, you believed that the Act's language was so imprecise that it just doesn't prohibit intact D&E's but also threatens all abortions, right?

[1878] A. Correct.

Q. So when you first read the Act as a practicing physician without conferring with government lawyers, you believed it was written in a way that threatened all abortions, right?

A. I wrote what I wrote.

Q. And you did believe that, right?

A. Correct. To be fair to all sides, I had reviewed the expert reports of your plaintiffs, and that may have added to my sense of urgency and concern.

Q. In fact, in your opinion, the wording of the Act is such that you can certainly understand why the plaintiffs' experts opined as they did concerning the Act's threat, right?

A. Correct.

Q. You still agree, don't you, Dr. Lockwood, that if the Act is not interpreted the way you believe appropriate, it is not only vague but worse, right?

A. If it is interpreted in a way that leads to a lack of access to pregnancy terminations, that would be a problem.

[1880:2-8] (Lockwood)

Q. In fact, you agree with very little in the findings that Congress made about the potential risks of partial-birth abortion, right?

A. That is correct.

Q. You think that there might be a slightly reduced risk of trauma in a D&X than in a D&E involving dismemberment, right?

A. Correct.

[1880:23-1881:7] (Lockwood)

Q. Doctor, you are not aware of any evidence that intact D&E is clearly dangerous to the mother, are you?

A. Certainly no evidence in terms of short-term risk to the [1881] mother, no.

Q. You are not aware of any specific evidence of risk in the long term, are you?

A. Not to the mother.

Q. In fact, you think intact D&E is comparable in safety to induction and dismemberment D&E, don't you?

A. More or less.

APRIL 13, 2004

[1967:16-17] (Anand)

Q. And you have never performed an abortion, have you?

A. No.

APRIL 14, 2004

[2093:2-4] (Sprang)

Q. Have you yourself performed abortions on live fetuses?

A. Only I would say in general exceedingly rarely. I have performed an abortion on a live fetus on one occasion.

[2151:23-25] (Sprang)

Q. You don't believe that it has been established that D&Xs have more complications than D&Es, is that correct?

A. Correct.

APRIL 15, 2004

[2332:20-2334:5] (Clark)

Q. In your opinion, if a woman is suffering from cardiomyopathy in her second trimester, would labor and delivery through the induction abortion method be contraindicated?

A. No. All three of these women were carried to full term.

Q. I see.

THE COURT: Your patients you are talking about?

[2333] THE WITNESS: Right.

A. Two of them ended up in the hospital for the last couple of months of their pregnancy. This was not an easy preg-

nancy. But ultimately they all went to term, they delivered vaginally, they took home healthy babies. They still have sick hearts, but we were able to, but treating the mother's heart with various pacemakers and drugs, able to carry her through so she could take home a healthy baby at the end of pregnancy.

But I want to make it clear that is not always the case. In fact, a serious cardiomyopathy is a perfectly fine, acceptable, wonderful reason to terminate the pregnancy. First or second trimester, that would be one of the reasons that you might terminate a pregnancy medically, yes.

THE COURT: Would that be to save her life?

THE WITNESS: That would be to save her life.

THE COURT: The heart condition is that serious?

THE WITNESS: Yes, that is true. Or the medical treatment to try to fix the heart condition just doesn't work and in fact she is going downhill despite it, yes.

Q. So that would be in a circumstance to advance maternal health, is that right?

A. Sure, exactly.

Q. In those circumstances where there would be a termination, would termination by medical induction abortion be appropriate?

A. Yes, it would. But, in fairness, the extraction procedure [2334] would also be appropriate. This would be one of those situations where it wouldn't matter one way or the other.

Q. By "extraction," you mean the D&E by dismemberment procedure?

A. Yes.

[2349:24-2350:14] (Clark)

Q. So, in and of itself, if you have von Willebran's disease, is that an indication for termination of pregnancy?

[2350] A. No, absolutely not. That's neither made worse nor made better by pregnancy, it just coexists. The woman's life will not be at an increased risk if she continues the preg-

nancy so it's irrelevant. But if she chooses to electively terminate, legally she can do so like any other woman.

Q. So, in those circumstances, would it be your opinion that D&E by dismemberment or medical induction abortion would be appropriate?

A. In the vast majority of cases, unless she's got it really bad and has a very bad bleeding tendency, in which case the medical route would be preferable.

THE COURT: When you say the medical, you mean medical induction?

THE WITNESS: Medical induction; yes, sir.

[2358:22-2359:17] (Clark)

Q. In your opinion what would be a safe and receivable method of abortion in cases where the woman had a prior vertical scar and sought an elective termination in the second trimester of a pregnancy?

[2359] A. Well, here is another indication where—I can't prove this is true by data but I believe it to be true that in fact the extraction procedure would probably be safer than the, that is the dismemberment procedure than the medical induction.

We know that at full term when there is a lot of tension on that uterus it is not appropriate to induce labor, that's primarily because the uterus can rupture and the baby can be damaged or killed.

Now, in a woman who is purposely terminating early on and the baby doesn't matter also, there is less tension on the uterus. I can't prove to you that there is any greater risk with medical induction but it would be a reasonable thing to think there might be, and so I would say as a general principle I would feel more comfortable in such women if they chose to terminate or we had to do it medically if they had some other condition, doing the dismemberment extraction procedure rather than medical.

[2399:19-24] (Clark)

Q. Dr. Clark, you consider yourself only moderately skilled in the provision of abortion, isn't that right?

A. Yes.

Q. You wouldn't consider yourself as expert in performing abortions as those who do it all the time, isn't that right?

A. By definition.

[2407:21-2408:7] (Clark)

Q. Doctor, it's your opinion that D&E may be safer at some gestational ages than medical induction when an incision has been made in the uterine fundus prior to the pregnancy, correct?

A. Yes. That's what I told Ms. Gowan, sure.

[2408] Q. You would agree that D&E beyond 20 weeks would be preferable to induction where a woman has a prior classical incision, right?

A. I've told you I believe it to be true. I can't prove it but I believe it to be true, yes.

Q. That's your opinion—

A. Yes.

[2408:18-24] (Clark)

Q. Okay, great.

That would be because D&E reduces the risk of uterine rupture, right, in that situation?

A. I think.

Q. You think it reduces the risk of uterine rupture in that situation?

A. I think.

[2411:7-12] (Clark)

Q. Cervical laceration is a potential risk of D&E, correct?

A. Or anything else that dilates the cervix mechanically, yes.

Q. And when you provide informed consent to your patients when you do a D&E, you tell them about the risk of laceration, correct?

A. Yes. Yes.

[2412:8-11] (Clark)

Q. Dr. Clark, you would agree, wouldn't you, that a woman who has experienced a preterm delivery is at a higher risk for preterm delivery in a subsequent pregnancy, correct?

A. True.

[2419:3-2420:13] (Clark)

Q. Section 14A talks about the risks of partial-birth abortion to women who undergo it, correct?

A. Yes.

Q. But you don't think that anyone could say that those are the risks of the procedure, do you?

A. Would you—let me go through them again here.

THE COURT: Would you like to have that read, is it? Do you want the question again?

THE WITNESS: No, I've got the question, I just want to read these risks to see if I agree in each case with your premise here.

Q. Of course.

A. Well, there is really only one of these which there is now some data to support, and that would be the risk of subsequent preterm birth, makes it difficult to carry a subsequent pregnancy to term.

The Chasen study gives evidence at least suggesting that that may in fact be true but these other things, in fact there is no evidence that would support that there is an increased risk of rupture, abruption, amniotic fluid embolism or trauma, and so I would disagree that one could make those statements there being no evidence that they are true.

THE COURT: You are not saying they're false, you are **[2420]** just saying that there is no evidence that you know of to say to prove they're true.

THE WITNESS: Correct. So I would disagree with the statement that says these things are risks.

THE COURT: Uh-huh.

THE WITNESS: I would disagree with that. I don't know if they're risks or not except the one, and that appears to be a risk.

BY MS. PARKER:

Q. Putting aside that one, you don't think anyone could say that those are risks of the procedure, do you?

THE COURT: He just said that.

THE WITNESS: Correct.

[2425:1-25] (Clark)

Q. Yes.

A. Spontaneous preterm birth occurred in 2 of 17, 11.8 percent pregnancy in the intact D&X grouped compared with 2 of 45, 4.4 percent in the dilatation and evacuation group.

Q. And then is there something at the end of that sentence?

A. Yes. Then it says P equals .30.

Q. Doctor, P equals .30 signifies the P value of the difference in outcomes between the intact group and the dismemberment group, correct?

A. Yes.

Q. And the P value is the measurement by which statistical significance is determined, is that right?

A. Using the method they used in this case, yes. There are other ways to do it too.

Q. And a P value of .30 is not a statistically significant difference, is it?

A. Correct.

Q. In fact, it means that there is a 30 percent chance that the different outcomes occurred by chance, is that right?

A. Fairly close. Statistically speaking you are on a little bit shaky ground.

Q. You wouldn't agree that it means that there is a 30 percent chance that these outcomes occur by chance?

A. I wouldn't quite phrase it like that but I will accept it. That is, there is a good chance that it occurred by chance.

[2427:12-2429:1] (Clark)

A. Both spontaneous preterm births in the intact D&X group occurred in women at high risk for prematurity. One woman who underwent intact D&X caused by PPROM at 20 weeks' gestation and subsequently delivered at 32 weeks, and the other underwent intact D&X at 23 weeks' gestation because of cervical incompetence with advanced cervical dilatation and subsequently delivered at 35 weeks.

Q. Doctor, PPROM means premature rupture of the membranes, is that right?

A. Yes.

Q. Doctor it is true, is it not that each of the women in the intact group were at a high risk for preterm birth in subsequent pregnancy regardless of undergoing the D&X procedure, is that right?

[2428] A. They were an increased risk for that, yes.

Q. Correct, they were at increased risk regardless of the D&X procedure, is that correct?

A. Right, and—

Q. In fact one of them—

THE COURT: You don't need to shout, counsel.

Q. One of them underwent the intact D&E procedure at 23 weeks as a result of experiencing PPROM, is that right?

A. Yes, that's true.

Q. And prior PPROM is in fact a risk factor for preterm birth, is that right?

A. Sure.

Q. And the second woman underwent intact D&X at 23 weeks because of cervical incompetence, correct?

A. Yeah.

Q. And prior cervical incompetence is in fact a risk factor for subsequent preterm birth, right?

A. Yeah.

Q. So, in fact, in each subsequent pregnancy each of these two women succeeded in carrying their pregnancies beyond 23 weeks, is that right?

A. Right.

Q. And they did that even though they both were at higher risk for subsequent preterm birth regardless of the abortion procedure that they had, is that right?

[2429] A. Exactly.

[2429:16-2430:30] (Clark)

Q. Dr. Clark, the numbers of preterm birth in subsequent pregnancy in this study are too small to really reach any conclusions, isn't that right?

A. Any conclusions other than the one that you've correctly reached already that there is a 30 percent chance this occurred by chance and a 70 percent chance that it in fact is a true, meaningful, increased risk other than that, one can reach no conclusions.

Q. This study identifies no increased risk for preterm birth in subsequent pregnancy in the two women who underwent [2430] dismemberment procedures and experienced subsequent preterm birth, is that right?

A. No, you said something in there wrong.

Q. Which was?

A. No increased risk in two women. You can't have a risk in a specific—that's just—part A doesn't go with part B, you need to ask that in a different manner.

Q. I will rephrase.

Doctor, the two women that we are talking about here, both of these women that we are talking about here already had a risk of preterm birth prior to undergoing any abortion procedure, is that right?

A. Right.

APRIL 16, 2004

[2487:21-2488:15] (Cook)

Q. Have you performed pregnancy terminations by methods other than induction?

A. On rare occasions I have.

Q. In the second trimester?

A. In the first and the second trimester.

[2488] Q. What other methods have you used in the second trimester?

A. In the second trimester, we will on occasion have to empty the uterus by a dismemberment procedure such as a D&E, and in the first trimester we may have to do a termination of pregnancy for issues like a molar gestation using a suction curettage method.

Q. Are most of your terminations on dead fetuses as opposed to living fetuses?

A. My experiences with second trimester termination of pregnancy by surgical techniques have been predominantly on babies that have already expired within 24 hours of the procedure. But my experiences with medical induction do sometimes involve the need to induce a pregnancy where the baby is still living at that time secondary to a worsening maternal condition.

[2548:5-23] (Cook)

Q. Doctor, are you aware that the plaintiff doctors in this case and their experts are claiming that D&X is safer than D&E because an intact extraction involves fewer instrument passes and fewer passes of sharp fetal fragments?

A. I am aware of that assertion.

Q. What is your view on whether the claimed fewer instrument passes and fewer passes of sharp fetal fragments offer safety advantages?

A. Well, on the surface it would make sense that the less manipulation involved in the uterus the less the risk for complication. However, just passing an instrument isn't necessarily equivalent to having to reach inside the uterus and convert a baby or turn a baby to a breech presentation,

which I would offer is a greater amount of intrauterine manipulation.

And again, that doesn't take into account my concerns about the delayed complications and the cervical dilation issues. But, intuitively, you could say it would make sense to presume less passes, could mean less complications of that narrow area of complication.

[2614:15-2615:6] (Cook)

Q. Would you agree, Doctor, that if a patient had premature rupture of membranes in one pregnancy, that patient would be at a greater risk to have premature delivery in a subsequent pregnancy?

A. Generally that's the case. However, it depends why they had premature ruptured membranes.

We have patients frequently who they're—who experience early ruptured membranes because they had vaginal bleeding from something called a subchorionic hematoma, or a blood clot underneath the bag of water. That's felt not to be a recurring risk factor.

[2615] We have people that have water that breaks prematurely because of external abdominal trauma, like in a car accident. That hopefully is also a non-recurring risk factor.

But if we cannot identify the risk factor, that population probably had a higher risk with subsequent populations.

APRIL 19, 2004

[2673:13-25] (Howell)

MS. CHAITEN: Your Honor, we also tender Dr. Howell as an expert in the quantitative and qualitative interpretation of clinical medical research pursuant to Federal Rule of Evidence 702.

THE COURT: Mr. Lane?

MR. LANE: Your Honor, we have no objection to that designation on the narrow scope for which he is offered by plaintiffs.

THE COURT: The Court does. I think he qualifies as an expert in medical history with some knowledge of quantitative and qualitative research, but I don't know about being an expert in it. With that designation, I will allow you to go ahead, Ms. Chaiten.

[2679:18-2680:11] (Howell)

Q. Doctor, how would you apply this example that you have given us to the issue of subsequent preterm labor in the Chasen study?

A. In order to understand whether or not the findings that were seen were due to chance or not, you would need to calculate the likelihood that they were simply due to chance. In this case, the authors have provided us with that calculation, and that calculation is that the P value is equal [2680] to .30.

What that means is, just like in the coin flip we would not be likely to conclude that the coin was not a true coin, similarly in this instance, given that in 30 percent of the times one would do this experiment one would see the same kind of difference or a greater difference, one would not conclude that this was a statistically significant difference.

Q. What would a statistically significant difference be?

A. The standard for statistically significant differences in medical research is either a P of less than or equal to .05 or a P of less than or equal to .01.

[2696:4-10] (Bowes)

"Q. Do you agree that during the course of the D&E in which the physician intends to effect dismemberment at the outset, it can occur that with merely one pass the entirety of the fetal body can be extracted intact up to the head?

"A. Do I agree that that might happen on some occasions?

"Q. Yes.

"A. Yes, it might happen."

[2700:2-11] (Bowes)

"Q. You would agree that there is a debate in the medical community as to whether it is the safest for some women in some circumstances?

"A. Yes.

"Q. And it's a position asserted by a responsible group of physicians?

"A. Yes.

"Q. But there is no consensus in the medical community that the procedure is never medically necessary?

"A. There is no consensus."

[2701:5-2703:13] (Bowes)

"Q. Do you recall, Dr. Bowes, giving deposition testimony in the New Jersey partial-birth abortion case in August 1998?

"A. Yes.

"Q. Do you recall that this question was asked and this answer given: 'What is the physician's intent in starting an induction abortion?

"'A. It is to end the pregnancy.'

"Do you recall testifying that way?

"A. If you're quoting from the testimony transcript, I did say that.

"Q. And do you agree with that today?

"A. Yes.

"Q. Do you recall testifying as follows:

"'Q. How about in doing a D&E?

"'A. Same'?

"A. Yes.

"Q. You would agree with that today?

"A. I agree with that.

"Q. And then question, 'How about in doing the Haskell procedure?

"'A. It's the same.'

[2702] "Do you remember that?

"A. Yes.

"Q. And do you agree with that today?

"A. Yes.

"Q. 'Q. And doing the McMahon procedure?'

"'A. The same.'

"Do you remember that?

"A. Yes.

"Q. And do you agree with that today?

"A. I agree with that.

"Q. 'Q. And in doing the four-step D&X procedure that ACOG describes, what is intent of such procedure?

"'A. The same.'

"Do you remember that?

"A. Yes.

"Q. And do you agree with that today?

"A. I agree with that.

"Q. 'Q. And what is that intent again?

"'A. To end the pregnancy.'

"Do you remember that?

"A. Yes.

"Q. Do you agree with that?

"A. Yes.

"Q. 'Q. In all of those cases, is the intent to end the pregnancy the safest way possible for the woman?' [2703] "And you answered 'Yes.' "Do you remember that?

"A. I don't remember saying that. I would disagree with that. I may have if what they're asking is in all of those cases is that the safest way to end that pregnancy.

"Q. No, that's not what they're asking.

"A. Well, tell me what they're asking.

"Q. The question is, 'In all those cases is the intent to end the pregnancy the safest way possible for the woman?' And you answered 'Yes.'

"A. Oh, the intent, yes.

"Q. And you agree with that today?

"A. Intent, yes."

[2706:19-2707:17] (Bowes)

"Q. Now, could you turn to page 4 and look at finding 14A. Why don't you read finding 14A to yourself. I don't think there is any need at this point to have you read the entire thing into the record, which would take some time.

"You would agree, would you not, Dr. Bowes, that there is no reliable and valid scientific evidence that supports the statements made in that finding, is there?

[2707] "A. No. There are risks that they mention here that are risks. But compared to other procedures that would have—I mean, you can't make this statement, I believe, in the absence of saying compared to what.

"Q. And, for example, with respect to the sentence that begins the paragraph, 'Partial-birth abortion poses serious risks to the health of the woman undergoing the procedure,' unless you have compared it to some other procedure through a valid scientific study, there is no reliable basis upon which anyone could make that statement, correct?

"A. That's correct.

Q. And you know of any reliable scientific evidence or study, Dr. Bowes, do you, that reliably demonstrates that 'partial-birth abortion' poses any of the risks enumerated here on a more serious or frequent basis than any other abortion procedure, do you?

"A. No.

[2708:19-22] (Bowes)

"Q. And all things equal, you agree, don't you, that minimization of instrumentation in the uterine cavity is a good thing?

"A. Intuitively, yes."

[2709:6-2710:6] (Bowes)

"Q. When a physician performs a D&E, Dr. Bowes, he or she tries to do it with as little trauma and blood loss for the woman as possible, correct?

"A. Yes.

"Q. And he or she tries to do it as quickly as possible, correct?

"A. Within the bounds of is being a safe procedure, yes.

"Q. And with as few insertions of the forceps as possible, correction?

"A. Inasmuch as that allows them to complete the procedure, yes."

At line 16 on page 155.

"Q. In testimony in New Jersey on October 2, 1998, you were asked the question: 'And don't you try to do it,' referring to a D&E, 'with as few insertions of the forceps as possible?' "And you answered 'Yes.'

"A. Yes.

"Q. Was that truthful testimony then?

"A. Yes.

"Q. And you agree with that now, don't you?

[2710] "A. Yes.

"Q. And you agree, don't you, Doctor, that intuitively, even if not conclusively, a technique that reduces the number of insertions of sharp instruments might offer some safety advantages?

"A. Yes."

[2714:14-23] (Bowes)

"Q. I'm asking you a distinct question. I'm asking whether, taking the ACOG statement and the plaintiffs' statements and the fact of the procedure being taught at what you identify as fine medical schools, there is a significant body of medical opinion, whether or not you agree with it, that the intact D&X may be the safest procedure for some women in some circumstances.

"A. If you would just eliminate the term 'significant,' I would say there is a group of practitioners who feel this procedure is acceptable."